U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4041–4060

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 11, 1954.*

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*For presence of a habit-forming narcotic without warning statement, see Nos. 4041, 4044; omission of, or unsatisfactory, ingredients statements, Nos. 4041, 4051, 4053; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4041, 4044; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4041, 4044.

282685—54——1

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4041. Misbranding of various drugs. U. S. v. James Allen Nolen (Radium Springs Sanitarium). Plea of nolo contendere. Defendant fined $2,000 and placed on probation for 1 year. (F. D. C. No. 30592. Sample Nos. 70301–K, 70304–K, 70722–K, 70723–K, 76931–K to 76943–K, incl., 85796–K to 85799–K, incl.)

INFORMATION FILED: July 24, 1951, Northern District of Oklahoma, against James Allen Nolen, trading as the Radium Springs Sanitarium, Salina, Okla.

ALLEGED SHIPMENT: Between the approximate dates of December 11, 1949, and April 15, 1950, from the State of Oklahoma into the States of Missouri, Kansas, and Texas, of quantities of *tablets for pain and nerves, rheumatism and gland tablets, laxative for stomach and kidneys, V E tonic tablets and capsules, tablets for rheumatism, nerves, and diabetes, powder for the treatment of cancer, douche powder, tablets for "sick" stomach, tablets for sore throat, tonsil disorders, "flue," and fever, capsules for the condition known as change of life, tablets and capsules for the treatment of cancer,* and *tablets for nervousness and sleeplessness.*

PRODUCT: Analyses disclosed that the *tablets for pain and nerves* contained aspirin, acetophenetidin, caffeine, and starch; that the *rheumatism and gland tablets* contained sodium salicylate, potassium iodide, vitamin B_1, and riboflavin; that a portion of the *laxative for stomach and kidneys* contained magnesium sulfate, magnesium acetate, potassium acetate, an emodin-bearing drug such as cascara, reducing sugar, and alcohol, and that another portion of the laxative contained magnesium sulfate, potassium acetate, alcohol, reducing sugar, and emodin; that the *V E tonic tablets* contained a large amount of yeast and calcium carbonate; that the *V E tonic capsules* contained chiefly yeast and lecithin; that the *tablets for rheumatism, nerves, and diabetes* contained salicylamide, vitamin B_1, and magnesium salicylate equivalent to salicylic acid; that the *powder for the treatment of cancer* contained bismuth subnitrate, colloidal aluminum hydroxide, activated charcoal, and the mucilaginous coating of blond psyllium seed; that the *tablets for "sick" stomach* contained bismuth subnitrate and phenobarbital; that the *tablets for sore throat, tonsil disorders, "flue," and fever* contained sulfathiazole, sugar, and starch; that the *capsules for the condition known as change of life* contained estrone, cornstarch, and lactose; that the *douche powder* contained boric acid, ammonium alum, berberine, and phenolic substances; that the *tablets for the treatment of cancer* contained lactose, cornstarch, and a trace of phenobarbital; that the *capsules for the treatment of cancer* contained calcium carbonate, sucrose, cornstarch, lactose, and animal tissues; and that the *tablets for nervousness and sleeplessness* contained phenobarbital, pentobarbital, starch, and calcium carbonate.

NATURE OF CHARGE: *Tablets for pain and nerves.* Misbranding, Section 502 (a), the statement on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of disorders of the nerves was false and misleading since the article would not be efficacious for such purposes; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient of the article, namely, aspirin, acetophenetidin, and caffeine.

Rheumatism and gland tablets. Misbranding, Section 502 (a), the statements on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of rheumatism and diseases of the glands were false and misleading since the article would not be efficacious for such purposes; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient of the article, namely, sodium salicylate, potassium iodide, and gelsemium extract.

Laxative for stomach and kidneys. Misbranding, Section 502 (a), the statement on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of diseases of the stomach and kidneys was false and misleading since the article would not be efficacious for such purposes; Section 502 (e) (2), the label of the article bore no statement containing the common or usual name of each active ingredient of the article, namely, epsom salt and cascara sagrada, and no statement of the quantity, kind, and proportion of alcohol present in the article; and, Section 502 (f) (1), the labeling of a portion of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease for which that portion of the article was intended to be used. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use of the article in those pathological conditions where its use may be dangerous to health, in that the article was a laxative and should not be used when abdominal pain (stomach ache, cramps, and colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis are present, and the labeling of the article failed to bear a warning that it should not be used in the presence of such symptoms; and, further, the labeling of the article failed to bear adequate warnings against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, in that frequent or continued use of the article may result in dependence upon laxatives to move the bowels, and its labeling failed to warn that frequent or continued use may have that result.

V E tonic tablets and capsules. Misbranding, Section 502 (a), the statements on the labels of the articles which represented and suggested that the articles would be efficacious in the cure, mitigation, and treatment of diabetes and that the articles possessed tonic properties were false and misleading since the articles would not be efficacious for such purposes and did not possess tonic properties; and, Section 502 (e) (2), the label of the *V E tonic tablets* failed to bear the common or usual name of the active ingredient of the article, namely, calcium carbonate.

Tablets for rheumatism, nerves, and diabetes. Misbranding, Section 502 (a), the statements on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of rheumatism, diabetes, and diseases of the nerves were false and misleading since the article would not be efficacious for such purposes; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient, namely, salicylamide and magnesium salicylate.

Powder for the treatment of cancer. Misbranding, Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient of the article, namely, bismuth subnitrate, colloidal aluminum hydroxide,

activated charcoal, and the mucilaginous coating of blond psyllium seed; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease for which the article was intended to be used.

Tablets for "sick" stomach. Misbranding, Section 502 (a), the statements on the label of the article which represented and suggested that the article would be efficacious in the treatment of "sick" stomach were false and misleading since the article would not be efficacious for such purpose. Further misbranding, Section 502 (d), the article contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (2), the label of the article bore no statement containing the common or usual name of each active ingredient of the article, namely, phenobarbital and bismuth subnitrate; and, Section 502 (f) (1), the labeling of a portion of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease for which that portion of the article was intended to be used.

Tablets for sore throat, tonsil disorders, "flue," and fever. Misbranding, Section 502 (a), the statements on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of sore throat, tonsil disorders, "flue," and fever were false and misleading since the article would not be efficacious for such purposes; Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient of the article, namely, sulfathiazole; Section 502 (f) (2), the labeling of the article bore no warnings against use of the article in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration; and, Section 502 (j), each tablet of the article contained 2 grains of sulfathiazole and was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "let 1 tab dissolve on tongue each 1 or 2 hours till relieved."

Capsules for the condition known as change of life. Misbranding, Section 502 (a), the statement on the label of the article which represented and suggested that the article would be efficacious in the relief of the symptoms associated with the condition commonly known as change of life was false and misleading since the article would not be efficacious for such purpose; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient of the article, namely, estrone.

Tablets for nervousness and sleeplessness. Misbranding, Section 502 (d), the article contained a chemical derivative of barbituric acid, namely, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease for which the article was intended to be used.

Further misbranding, Sections 502 (b) (1) and (2), the *tablets for pain and nerves, rheumatism and gland tablets, laxative for stomach and kidneys, V E tonic tablets and capsules, tablets for rheumatism, nerves, and diabetes, powder for the treatment of cancer, tablets for "sick" stomach, tablets for sore throat, tonsil disorders, "flue," and fever, capsules for the condition known as change of life,* and *tablets for nervousness and sleeplessness* failed to bear labels containing the place of business and, in some instances, the name of the manufacturer, packer, or distributor; and such articles failed also to bear labels containing a statement of the quantity of the contents.

Douche powder and tablets and capsules for the treatment of cancer. Misbranding, Section 502 (f) (1), the label of the articles failed to bear adequate directions for use in the treatment of cancer, which was the disease for which the articles were intended to be used.

Further misbranding, Section 502 (a), the statement "Nolen M. D.," appearing on the label of a portion of the *laxative for stomach and kidneys*, and the statement "Dr. Nolen," appearing on the label of the *tablets for nervousness and sleeplessness* and on the label of a portion of the *rheumatism and gland tablets* and *tablets for "sick" stomach*, were false and misleading. Such statements represented and suggested that the defendant, James Allen Nolen, possessed the medical qualifications required for the practice of medicine in the State of Oklahoma and was licensed to practice medicine in that State, whereas the defendant did not possess such medical qualifications and was not licensed to practice medicine in such State.

DISPOSITION: November 21, 1951. The defendant having entered a plea of nolo contendere, the court fined him $2,000 and placed him on probation for 1 year.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4042. Misbranding of dextro-amphetamine sulfate tablets and sulfathiazole tablets. U. S. v. Griffin-Robertson Drug Co. and Gilbert C. Griffin and Marcus W. Robertson. Pleas of nolo contendere by individual defendants. Action against company dismissed. Each individual defendant fined $50. (F. D. C. No. 34316. Sample Nos. 46528–L to 46531–L, incl.)

INFORMATION FILED: December 5, 1952, Northern District of Mississippi, against the Griffin-Robertson Drug Co., a partnership, Corinth, Miss., and Gilbert C. Griffin and Marcus W. Robertson, partners in the partnership.

NATURE OF CHARGE: On or about June 21 and 22, 1952, while a number of *dextro-amphetamine sulfate tablets* and *sulfathiazole tablets* were being held for sale at the Griffin-Robertson Drug Co., after shipment in interstate commerce, the defendants caused quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: February 11, 1953. Pleas of nolo contendere having been entered by the individual defendants, the court fined each individual $50. The court ruled that the action did not lie against a partnership and therefore dismissed the action against the partnership defendant.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS *

4043. Misbranding of Seconal Sodium capsules. U. S. v. Louis E. Krouse (Main Cut Rate), and Daniel Krowitz. Pleas of not guilty. Tried to the court and jury. Verdict of guilty. Fine of $1,000 against Defendant Krouse and $500 against Defendant Krowitz and sentence of 1 year in jail against each defendant. Jail sentences suspended and each defendant placed on probation for 5 years. (F. D. C. No. 33733. Sample No. 25704–L.)

INFORMATION FILED: December 30, 1952, Eastern District of Pennsylvania, against Louis E. Krouse, trading as Main Cut Rate, Philadelphia, Pa., and against Daniel Krowitz, also known as David Krouse, an employee of Main Cut Rate.

ALLEGED VIOLATION: On or about June 5, 1951, while a number of *Seconal Sodium capsules* were being held for sale at Main Cut Rate, after shipment in interstate commerce, the defendants caused one bottle of the capsules to be dispensed in the original bottle in which the capsules had been shipped in interstate commerce, without a prescription of a physician, which act resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the capsules bore no directions for use (the bottle in which the capsules were shipped in interstate commerce bore no directions for use since it was exempt from such requirement by the label statement "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendants in dispensing the drug without a physician's prescription caused the exemption to expire).

DISPOSITION: The defendants having entered pleas of not guilty, the case came on for trial before the court and jury on March 4, 1953, and was concluded on March 6, 1953, with the return of a verdict of guilty by the jury. Thereafter, a motion for a new trial, or, in the alternative, for a judgment of acquittal, was filed on behalf of the defendants, and on June 23, 1953, the motion was dismissed for failure of the defendants to pursue the matter further.

On July 22, 1953, the court fined Defendant Krouse $1,000 and Defendant Krowitz $500 and sentenced each defendant to 1 year in jail. The jail sentences were suspended, and each defendant was placed on probation for 5 years.

4044. Misbranding of methyltestosterone tablets, dextro-amphetamine sulfate tablets, thyroid tablets, and tablets containing a mixture of mannitol hexanitrate and phenobarbital. U. S. v. Fay C. Dyes and Milton J. Reynaud. Pleas of nolo contendere. Fine of $150 against each defendant. (F. D. C. No. 33742. Sample Nos. 31026–L, 34174–L, 34377–L to 34379–L, incl., 34382–L.)

INFORMATION FILED: January 19, 1953, Western District of Missouri, against Fay C. Dyes and Milton J. Reynaud, partners in the partnership of Dyes Drug Store, Aurora, Mo.

ALLEGED VIOLATION: On or about March 19 and 20, 1952, while a number of *methyltestosterone tablets*, *dextro-amphetamine sulfate tablets*, *thyroid tablets*, and *tablets containing a mixture of mannitol hexanitrate and phenobarbital* were being held for sale at Dyes Drug Store, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be re-

*See also No. 4041.

packed and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), all of the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *tablets containing a mixture of mannitol hexanitrate and phenobarbital* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: April 2, 1953. Pleas of nolo contendere having been entered, the court fined each defendant $150.

4045. Action to enjoin and restrain the interstate shipment of Renesol or Renesol Treatment. U. S. v. Renesol Corp., Charles I. Goldblatt, and Nathan Katz. Consent decree of injunction. (Inj. No. 233.)

COMPLAINT FILED: January 18, 1952, District of New Jersey, against the Renesol Corp., Jersey City, N. J., and Charles I. Goldblatt, president and treasurer, and Nathan Katz, vice president and secretary of the corporation.

ALLEGED VIOLATION: The complaint alleged that the defendants were engaged in the business of manufacturing, distributing, and selling an article of drug consisting of a phenobarbital compound under the name of *Renesol* or *Renesol Treatment*. The complaint alleged further that the defendants were introducing and delivering for introduction into interstate commerce the above-mentioned article in a misbranded condition.

NATURE OF CHARGE: Misbranding Section 502, (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of the diseases and conditions for which the article was prescribed, recommended, and suggested, namely, epilepsy and symptoms of epilepsy.

DISPOSITION: September 2, 1952. The defendants having consented to the entry of a decree, the court entered a decree permanently enjoining and restraining the defendants from introducing and delivering for introduction into interstate commerce the above-mentioned article, or any similar article, which was misbranded, as alleged in the complaint, and also from dispensing such article contrary to the provisions of Section 503 (b). (This section provides, in part, that certain drugs shall be dispensed only upon a written prescription of a practitioner licensed by law to administer such drugs.)

It also was provided in the decree that nothing contained therein should be deemed to prejudice any rights which the defendants might have under Section 801 (d) of the Act, or of any other law, regulation, or requirement relating to export.

4046. Action to enjoin and restrain the interstate shipment of Muscle-Rub. U. S. v. Pauline Harrison (Muscle-Rub Distributors), and Herman H. Kronberg. Consent decree of injunction. (Inj. No. 258.)

COMPLAINT FILED: January 5, 1953, Southern District of California, against Pauline Harrison, trading as the Muscle-Rub Distributors, Los Angeles, Calif., and Herman H. Kronberg, general manager of the business.

ALLEGED VIOLATION: The complaint alleged that the defendants distributed a certain counter-irritant drug under the name of *Muscle-Rub*, which consisted of a mixture of isopropyl alcohol, ethyl alcohol, witch hazel, camphor, menthol, and methyl salicylate. The complaint alleged further that the defendants were introducing and delivering for introduction into interstate commerce the above-mentioned article in a misbranded condition, and that the defendants were doing acts with respect to the article while held for sale after shipment in interstate commerce, which resulted in the article becoming misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was false and misleading since it represented, implied, and suggested that the article was efficacious for the cure and relief of pains due to arthritis, rheumatism, lumbago, neuritis, sciatica, neuralgia, bruises, sprains, foot irritations, and other crippling conditions, whereas the article was not efficacious for such purposes; Section 502 (f) (1), the labeling of the article did not bear adequate directions for use since it did not contain a statement of all the purposes and conditions for which the article was intended by the defendants and sufficient information to enable a layman to intelligently and safely attempt self-medication for the purposes and conditions for which it was intended; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against unsafe methods and duration of use since the labeling failed to state that the article should be kept away from the eyes and mucous membranes and should be rubbed in gently and not excessively.

DISPOSITION: January 6, 1953. The defendants having consented to the entry of a decree, the court entered a decree permanently enjoining and restraining the defendants from introducing and delivering for introduction into interstate commerce the article in question or any similar article which was misbranded as alleged in the complaint, and from doing any act with respect to any such article while held for sale after shipment in interstate commerce, which would result in the article becoming misbranded as alleged.

4047. Misbranding of glandular products. U. S. v. 3 Cartons, etc. Tried to the court. Verdict for the Government. Decree of condemnation. (F. D. C. No. 28474. Sample Nos. 68509–K, 68511–K to 68515–K, incl.)

LIBEL FILED: December 20, 1949, Western District of Washington.

ALLEGED SHIPMENT: On or about July 21, September 21, October 28, November 7, 18, and 30, and December 7, 1949, by the W. H. Grew Mfg. Co., from Salt Lake City, Utah.

PRODUCT: 3 30-capsule cartons of *No. 26 Formula GM capsules*, 5 30-capsule cartons of *No. 6 Formula GE–5 capsules*, 5 30-capsule cartons of *No. 29 Formula GM–3 capsules*, 4 30-capsule cartons of *No. 33 Formula GM–7 capsules*, 5 30-capsule cartons of *No. 38 Formula GM–12 capsules*, and 14 30-perle cartons of *No. 105 androgenic hormone perles*, at Seattle, Wash.

LABEL, IN PART: "No. 26 Formula GM 30 Capsules Each Capsule Contains: (Apoth) Suprarenal Cortex 4 grs., Spleen 1 gr., Parathyroid 1/20 gr., and Vegetable base q. s. Caution: To be used only under the direction of a Doctor. There is no scientific evidence that Suprarenal Cortex, Spleen or Parathyroid is therapeutically active when taken orally."; "No. 6 Formula GE–5 30 Capsules Each Capsule Contains: (Apoth) Cardiac 5 grs., and Vegetable base q. s. Caution: To be used only under the direction of a Doctor. There is no scientific evidence that Cardiac is therapeutically active when taken orally."; "No. 29 Formula GM–3 30 Capsules Each Capsule Contains: (Apoth) Lym-

phatic 3 grs., Spleen 2 grs., Parathyroid 1/12 gr., and Vegetable base q. s. Caution: To be used only under the direction of a Doctor. There is no scientific evidence that Lymphatic, Spleen or Parathyroid is therapeutically active when taken orally."; "No. 33 Formula GM–7 30 Capsules Each Capsule Contains: (Apoth) Kidney 4 grs., Duodenum ¾ gr., Pancreas ¾ gr., and Vegetable base q. s. Caution: To be used only under the direction of a Doctor. There is no scientific evidence that Kidney, Duodenum or Pancreas is therapeutically active when taken orally."; "No. 38 Formula GM–12 30 Capsules Each Capsule Contains: (Apoth) Lymphatic 2 grs., Spleen 1 gr., and Vegetable base q. s. Caution: To be used only under the direction of a Doctor. There is no scientific evidence that Lymphatic or Spleen is therapeutically active when taken orally."; and "No. 105 30 Perles Androgenic Hormone ½ Capon Unit Per Perle For Oral Use Only. Androgenic Substance derived from testicular tissue dissolved in corn oil. Caution: To be dispensed only by or on the prescription of a physician. There is no scientific evidence that Androgenic substance is therapeutically active when taken orally."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

DISPOSITION: Basic Endocrines Sales Co., Inc., Seattle, Wash., appeared as claimant and filed an answer denying that the products were drugs and that they were misbranded, and alleging as an affirmative defense that the products were sold to licensed doctors; that the products could not be obtained by the public except through a licensed doctor; that no claims for the products were made other than the language appearing upon the labels; and that a large number of doctors demanded the products for use in their professional practice and believed that the products were beneficial.

The claimant filed also a number of requests for admissions, to which objections were raised by the Government. Hearing on the objections was heard by the court on June 9, 1950, at the conclusion of which, the court overruled some of the objections and sustained the others. Answers to the requests on which objections were overruled were filed. The Government then filed a set of written interrogatories upon the claimant. An amended answer was filed on or about July 19, 1950, in which the claimant deleted its affirmative defense, and on July 24, 1950, the claimant filed its objections to all interrogatories except for two which it answered. A hearing on the objections to the interrogatories resulted in the court overruling certain objections and sustaining the others.

On January 22, 1951, the case was removed from the Western District of Washington for trial in the Southern District of California. Following the removal, extensive pretrial proceedings were had, resulting in the submission of the case to the court upon the basis of a stipulated record.

On November 20, 1952, the court handed down the following findings of fact and conclusions of law:

CARTER, *District Judge:*

FINDINGS OF FACT

"(1) During 1949, the W. H. Grew Manufacturing Company shipped various quantities of the following articles from Salt Lake City, Utah, to Seattle, Washington, consigned to the Basic Endocrines Sales Company, Inc., 1219 Northern Life Tower:

No. 26 Formula GM
No. 6 Formula GE–5

No. 29 Formula GM–3
No. 38 Formula GM–12
No. 33 Formula GM–7
No. 105 Androgenic Hormone

"(2) On December 20, 1949, the United States filed a Libel of Information in the U. S. District Court for the Western District of Washington, No. 15418, alleging that said articles were drugs and were misbranded within the meaning of 21 U. S. C. 352 [502] (f) (1) in that their labeling failed to bear adequate directions for use.

"(3) Pursuant to said Libel and process issued thereunder, the United States Marshal for the Western District of Washington seized said articles in the possession of said Basic Endocrines Sales Company, Inc., at Seattle, Washington, which was then holding them to fill orders from customers.

"(4) The Basic Endocrines Sales Co., Inc., intervened as Claimant and filed an Answer, and later an Amended Answer, denying that the articles were either drugs or misbranded. Subsequently, by Order of Removal dated January 22, 1951, the cause was transferred by the District Court for the Western District of Washington to this District for trial.

"(5) Extensive pretrial proceedings were had in this District and the case was submitted upon a stipulated record.

"(6) On January 30, 1952, by Stipulation And Order As To Partial Withdrawal Of Claims And Amended Answer, the Claimant withdrew its Claim and Amended Answer with respect to the article designated as 'No. 105 Androgenic Hormone.' Claimant asserted it was no longer distributing this article and therefore had no reason to contest the allegations in the Libel regarding this article.

"(7) The labeling of the articles under seizure consists solely of the labels affixed to the individual cartons. One of these labels, typical of all, reads in its entirety as follows:

No. 6 Formula GE–5 30 Capsules
Each Capsule Contains: (Apoth) Cardiac 5 grs., and Vegetable base q. s.
Caution: To be used only under the direction of a Doctor.
There is no scientific evidence that Cardiac is therapeutically active when taken orally.
Manufactured for and distributed by
BASIC ENDOCRINES SALES CO., INC—SEATTLE, WASH.

"(8) Claimant concedes that none of these articles has any therapeutic value.

"(9) Claimant has been doing an interstate business in the distribution of these products for the past 25 years. Claimant's main office is in Seattle, Washington, and it has branch offices in Los Angeles, San Francisco, Chicago, Detroit, and Cleveland. All literature used by the various branch offices emanates from the Seattle office. Sales promotion practices of the firm are the same throughout the country; the same literature is used and the same representations are made for its products in all the branch offices.

"(10) Each product has a rather long identifying name—e. g., 'No. 6 Formula GE–5.' Claimant has from time to time used different identifying symbols for its products but the letters and number following the word 'Formula' have remained constant. Thus 'Formula GE–5' has been unchanged and has referred to the same product though sometimes preceded by a number other than 'No. 6.'

"(11) During the past 17 years, Claimant's representatives have distributed many items of literature to customers and prospective customers to induce orders for Claimant's products. Exhibits before the Court include 18 specimens of such literature, ranging in size from a 1-page chart to a 126-page booklet. These Exhibits are identified as follows:

Exhibit 1 – Booklet entitled "Basic Endocrines" (5th Edition)—published about 1937.
Exhibit 2 – Indications Chart—1935.

Exhibit 3 – Booklet entitled "Basic Foods and Endocrines" subtitle "Formulae and Reference Guide"—1935.

Exhibit 5 – Booklet entitled "Basic Endocrines from Embryo Throughout Life" (6th Edition, 1939).

Exhibit 6 – Leaflet entitled "Basic Endocrines"—about 1940.

Exhibit 8 – Booklet entitled "Basic Endocrines from Embryo Throughout Life"—1945.

Exhibit 9 – Leaflet entitled "Androgenic Substance in Corn Oil"—1945.

Exhibit 11 – Booklet entitled "Index of Basic Endocrines."

Exhibit 12 – Leaflet entitled "Dysmenorrhea" and "Nephritis, etc."

Exhibit 13 – Booklet entitled "Basic Endocrines from Embryo Throughout Life" and "Theory and Use of Basic Endocrines"—1941.

Exhibit 14 – Magazines entitled "Endogram"—July 1947, August 1949, April 1949, January 1949.

Exhibit 15 – Booklet entitled "Basic Endocrines from Embryo Throughout Life" (Price List, 1947).

Exhibit 19 – Three miniature leaflets entitled "Basic Endocrines from Embryo Throughout Life"—Volume 1, No. 1, No. 3, and No. 4.

Exhibit 20 – Two miniature leaflets entitled "Basic Endocrines from Embryo Throughout Life"—Volume 1, No. 5 and No. 6.

Exhibit 22 – Indications or Symptom Chart.

Exhibit 23 – Chart entitled "Foundation of Basic Endocrines."

Exhibit 24 – Specimens of current labels of articles under seizure.

Exhibit 25 – Booklet entitled "Basic Endocrines from Embryo Throughout Life"—1938 Edition.

"(12) Despite Claimant's concession that the products under seizure have no therapeutic value, Claimant's literature has consistently represented these products as efficacious in the treatment, mitigation, and prevention of many ailments including some of the most serious that afflict mankind.

"(13) Claimant's Secretary represents that in recent years the Claimant has ordered its representatives to cease distributing said literature, but actual distribution of such literature has nevertheless been continued by its representatives. Claimant's representatives or detail men have given or 'loaned' to prospective customers so-called 'personal copies' of some items of this literature containing the most comprehensive therapeutic claims for the products under seizure.

"(14) Claimant's representatives or detail men have also freely given their customers oral advice regarding the disease conditions for which they claimed these products were indicated as well as the dosages in which they should be prescribed in treating those conditions.

"(15) Many of Claimant's customers who had apparently not received its literature (making therapeutic claims) in recent years, had in their possession identical or similar literature which Claimant had distributed 7—14 years ago, and these customers relied upon such literature and the aforesaid oral advice in ordering and prescribing the products in question.

"(16) The products under seizure are labeled to declare the presence of minute quantities of animal glands in a vegetable base. For example, 'No. 6 Formula GE–5' is represented to contain 5 grains of cardiac or animal heart in each capsule. It would require 1,400 capsules, each containing five grains of cardiac, to comprise one pound of cardiac substance.

"(17) The articles under seizure are all drugs within the meaning of 21 U. S. C. 321 (g) (2) since they were intended for use in the treatment, mitigation, and prevention of many disease conditions. Such intended use is neither negated nor camouflaged by the following disclaimer which in substance appears on the label of each article: 'There is no scientific evidence that Cardiac is therapeutically active when taken orally.'

"(18) The labeling of said drugs does not mention any disease condition.

"(19) The labeling of said drugs fails to bear adequate directions for use in that it fails to state the purposes and conditions for which said drugs are intended.

CONCLUSIONS OF LAW

"(1) The articles here involved were shipped in interstate commerce from Salt Lake City, Utah, to Seattle, Washington.

"(2) Said articles were seized by the United States Marshal for the Western District of Washington within the jurisdiction of the U. S. District Court for that District, pursuant to 21 U. S. C. 334 (a). The jurisdiction of this Court derives from an Order of the U. S. District Court for the Western District of Washington removing the instant cause to this District on application of the Claimant, pursuant to 21 U. S. C. 334 (a).

"(3) For the purposes of Section 201 (g) (2) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. 321 (g) (2)], it is the *intended use* of an article which determines whether it is a drug, regardless of its inherent properties or dictionary definition. By this statutory definition, an article is a drug if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.

"(4) An article which is a food under 21 U. S. C. 321 (f) may also be a drug under 21 U. S. C. 321 (g) (2) depending upon its intended use.

"(5) There is no distinction between a representation that an article has *value* in the treatment of heart trouble, and a representation that an article has *nutritional value* in the treatment of heart trouble. Either of these representations will make the article a drug within the meaning of 21 U. S. C. 321 (g) (2). The use of the term 'nutritional' in the sales promotion of an article will not immunize it from the drug provisions of the Federal Food, Drug, and Cosmetic Act if it is in fact intended for therapeutic purposes.

"(6) 'The Act is not concerned with the purification of the stream of commerce in the abstract. The problem is a practical one of consumer protection, not dialectics.' *U. S.* v. *Urbeteit*, 335 U. S. 355, 357–358 (1948).

"(7) If an article is intended for use in the cure, treatment, mitigation, or prevention of disease, such article is a drug under 21 U. S. C. 321 (g) (2) and it is immaterial whether it is designated as a therapeutic agent or as a nutritional support.

"(8) In ascertaining the intended use of an article to determine whether it is a drug under 21 U. S. C. 321 (g) (2), the Court may look to any source which discloses the intended use.

"(9) Where a person has set in motion forces that result in creating an impression that an article has value in the treatment of disease, he cannot avoid the legal consequences of such action by a disclaimer in the labeling asserting there is no scientific evidence that the article has therapeutic value.

"(10) Where a distributor has given its customers literature which makes therapeutic claims for its products, and years later the customers continue to rely upon that literature in ordering and prescribing those products, such literature may properly be examined by a Court in seeking to determine whether the products are drugs within the meaning of 21 U. S. C. 321 (g) (2).

"(11) Nor is it significant whether the distributor has stopped giving out the literature. Where a person has set in motion forces that result in the continued profitable demand for his products, he cannot continue to fill that demand and yet avoid all responsibility for those forces by disclaiming he is still setting them in motion.

"(12) Each of the articles under seizure is a drug within the meaning of 21 U. S. C. 321 (g) (2).

"(13) A drug is misbranded under 21 U. S. C. 352 [502] (f) (1) unless its labeling bears 'adequate directions for use.'

"(14) The labeling of a drug does not bear 'adequate directions for use' unless, among other things, it states the purposes and conditions for which the drug is intended.

"(15) All of the drugs under seizure were misbranded when introduced into and while in interstate commerce in that the labeling of each drug failed to state the purposes and conditions for which such drug was intended.

"(16) All of said drugs are subject to condemnation and destruction pursuant to 21 U. S. C. 334 (a) and (d), and libelant is entitled to a decree ordering such condemnation and destruction.

"(17) Libelant is entitled to its costs herein, pursuant to 21 U. S. C. 334 (e)."

On November 20, 1952, pursuant to the above findings and conclusions, judgment of condemnation was entered and the court ordered that the products be destroyed.

4048. Misbranding of Lipitrons capsules. U. S. v. 5 Bottles, etc. (F. D. C. No. 34159. Sample No. 14547–L.)

LIBEL FILED: December 4, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about September 24 and November 10, 1952, by Vitamin Industries, Inc., from Omaha, Nebr.

PRODUCT: 5 100-capsule bottles and 2 250-capsule bottles of *Lipitrons capsules* at Denver, Colo.

RESULTS OF INVESTIGATION: A poster entitled "If You Are Over 35" and on display in the store of the consignee had been supplied by the Vitamin Industries, Inc. In addition, there appeared in the September 21, 1952, issue of a local newspaper an advertisement in which *Lipitrons capsules* were offered for persons more than 35 years of age suffering from the various conditions indicated below. This advertisement was printed from a mat furnished by Vitamin Industries, Inc.

LABEL, IN PART: (Bottle) "Guardian * * * Super Forte Lipitrons Dietary Supplement Improved B Complex Vitamin C Iron * * * Each Capsule Contains: Vitamin B_1 15 mgm. Vitamin B_2 6 mgm. Vitamin C 50 mgm. Niacinamide 30 mgm. Calcium Pantothenate 3 mgm. Vitamin B_6 0.5 mgm. Liver Concentrate 30 mgm. Choline Dihydrogen Citrate 20 mgm. Inositol 20 mgm. Iron as Ferrous Gluconate 30 mgm. Folic Acid 0.1 mgm. Vitamin B_{12} USP (Crystalline) 3 mcg. dl-Methionine 20 mgm."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements appearing on the poster which accompanied the article were false and misleading: "If you are over 35 If you are getting that Growing Old Feeling * * * A True Geriatric Formula Designed Especially For Advanced Age Groups To Help You Enjoy Life Again." These statements, when read and interpreted in the light of the above-mentioned newspaper advertisement, represented and suggested and created the impression that the article was effective in the treatment of persons more than 35 years old suffering from constant tiredness, lack of vigor and energy, nervousness, and a rundown condition; that it was effective to supply extra vigor and extra energy; that it was effective to enable one to really begin to enjoy life again; that it was effective to attack the basic causes of the tired feeling, poor appetite, loss of weight and strength, and insomnia or sleeplessness; that it was effective to insure persons past 35 against fear of the feeling of advancing age; and that it was effective to help build new, red blood. The article was not effective in the treatment of persons over 35 years of age suffering from such conditions, and it was not capable of fulfilling the promises of benefit stated and implied. The article was misbranded in the above respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which the article was intended, namely, for persons more than 35 years old suffering from constant tiredness, lack of vigor and energy, weakness, nervousness, and a rundown condition; to supply extra vigor and extra energy; to enable one to really begin to enjoy life again; to attack the basic causes of the tired feeling, poor appetite, loss of weight and strength, and insomnia or sleeplessness; to

insure persons past 35 against fear of the feeling of advancing age; and to help build new, red blood, which were the conditions and purposes for which the article was offered in the September 21, 1952, issue of a local newspaper. The article was misbranded in this respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: January 23, 1953. Default decree of condemnation. The court ordered that the product be delivered to the hospital ward of a Federal institution, for use in the treatment of patients requiring the prescribing of vitamin preparations.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4049. Adulteration and misbranding of conjugated estrogen tablets. U. S. v. 3 Bottles, etc. (F. D. C. No. 33586. Sample Nos. 41220–L, 41221–L.)

LIBEL FILED: September 12, 1952, Western District of Washington.

ALLEGED SHIPMENT: On various dates from outside the State of Washington.

PRODUCT: 3 500-tablet bottles of *No. 105 conjugated estrogen tablets* and 5 500-tablet bottles and 2 1,000-tablet bottles of *No. 106 conjugated estrogen tablets* at Seattle, Wash.

Analysis showed that the *No. 105 conjugated estrogen tablets* and the *No. 106 conjugated estrogen tablets* contained 0.94 milligram and 0.475 milligram, respectively, per tablet of conjugated estrogens expressed as sodium estrone sulfate.

LABEL, IN PART: (Bottle) "No. 105 1.25 mg. [or "No. 106 0.625 mg."] Estrogenic Substances (Water-Soluble) Conjugated Estrogens (Equine) Each tablet contains 1.25 mg. [or "0.625 mg."] of estrogens in their naturally occurring, water-soluble conjugated form, expressed as sodium estrone sulfate. Distributed by Palmer & Co. Seattle, Wash."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the *No. 105 conjugated estrogen tablets* and the *No. 106 conjugated estrogen tablets* differed from that which they purported and were represented to possess.

Misbranding, Section 502 (a), the label statements "Each tablet contains 1.25 mg. of estrogens in * * * conjugated form, expressed as sodium estrone sulfate" and "Each tablet contains 0.625 mg. of estrogens in * * * conjugated form, expressed as sodium estrone sulfate," respectively, were false and misleading as applied to the tablets, which contained less than the declared amounts of estrogens in conjugated form.

DISPOSITION: April 3, 1953. Default decree of condemnation and destruction.

4050. Adulteration and misbranding of vitamin B complex capsules. U. S. v. 700 Capsules, etc. (F. D. C. No. 34539. Sample No. 56845–L.)

LIBEL FILED: January 7, 1953, Northern District of Ohio.

ALLEGED SHIPMENT: On or about September 29, 1952, by Fellows Medical Mfg. Co., Inc., from New York, N. Y.

PRODUCT: *Vitamin B complex capsules.* 700 capsules and 32 bottles, each bottle containing 50 capsules, at Cleveland, Ohio. Analysis showed that the product contained approximately 76 percent of the declared amount of vitamin B_1.

LABEL, IN PART: "Fellows * * * Vitamin B-Complex Capsules Each Capsule Contains * * * Thiamine Hydrochloride (10 M. D. R.) 10 Mg. * * * Therapeutic."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Each Capsule Contains * * * Thiamine Hydrochloride (10 M. D. R.) 10 Mg." was false and misleading since the product contained less than the labeled amount of thiamine hydrochloride (vitamin B_1) per capsule.

DISPOSITION: March 5, 1953. Default decree of condemnation and destruction.

4051. Adulteration and misbranding of isopropyl alcohol rubbing compound. U. S. v. 38 Cases * * *. (F. D. C. No. 34665. Sample No. 38914–L.)

LIBEL FILED: On or about February 19, 1953, Western District of Virginia.

ALLEGED SHIPMENT: On or about October 28, 1952, by the Best Sales Co., from Middlesboro, Ky.

PRODUCT: 38 cases, each containing 12 1-pint bottles, of *isopropyl alcohol rubbing compound* at Pennington Gap, Va.

LABEL, IN PART: (Bottle) "Best Rubbing Alcohol 70% Isopropyl Compound By Volume * * * Best Sales Co. Cincinnati, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Isopropyl Alcohol Rubbing Compound," a drug, the name of which is recognized in the National Formulary, and its strength differed from the official standard. The standard provides that an isopropyl alcohol rubbing compound contains not less than 68 percent of isopropyl alcohol, whereas the article contained less than 68 percent of isopropyl alcohol. (Examination showed that the article contained from 13.8 percent to 49.8 percent of isopropyl alcohol by volume.)

Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear an accurate statement of the proportion of alcohol contained therein.

DISPOSITION: April 14, 1953. Default decree of condemnation and destruction.

4052. Adulteration and misbranding of clinical thermometers. U. S. v. 5 Dozen * * *. (F. D. C. No. 34450. Sample No. 55258–L.)

LIBEL FILED: December 19, 1952, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 23, 1952, by Guardian Thermometer Co., Inc., from New York, N. Y.

PRODUCT: 5 dozen *clinical thermometers* at Erie, Pa.

LABEL, IN PART: "Clinical Fever Thermometers Rectal" and "Globe Fever Thermometer Rectal."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statement appearing in the labeling was false and misleading as applied to the article, which failed to meet the tests laid down in Commercial Standard CS1–32 Department of Commerce for pigment retention: (On 1 dozen container and individual carton) "This thermometer has been tested, found to comply with the requirments of the Department of Commerce Commercial Standard CS1–32." (Examination of 5 thermometers showed that all failed to meet the CS1–32 test for loss of pigment.)

DISPOSITION: January 23, 1953. Default decree of condemnation. The court ordered that the product be delivered to a local hospital.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

4053. Misbranding of Cal-Sal tablets. U. S. v. 12 Display Cartons * * *. (F. D. C. No. 34436. Sample No. 54088–L.)

LIBEL FILED: December 17, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 15 and November 24, 1952, by the Commerce Drug Co., from Brooklyn, N. Y.

PRODUCT: 12 display cartons, each containing 16 bottles in individual boxes, of *Cal-Sal tablets* at Chicago, Ill.

LABEL, IN PART: (Display carton) "Cal-Sal with Vitamin B_1 Relief of Symptoms Arthritis Rheumatism 1⅓ Doz."; (box and bottle) "100 Tablets Cal-Sal with Vitamin B_1 for relief of symptoms Arthritis Rheumatism Active Ingredients: Calcium Succinate Acetyl Salicylic Acid Manganese Salicylate Thiamin Chloride 1 mg. Caffeine."

NATURE OF CHARGE: Misbranding, Section 502 (a) the following statements in the labeling of the article, namely, (display carton, box, and bottle) "* * * Relief of Symptoms Arthritis Rheumatism * * *," "* * * effective * * *," "When symptoms subside * * *," and "For most effective results, continue using for a few months after relief from pain has been obtained * * *," were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for arthritis and rheumatism, whereas the article was not an adequate and effective treatment for arthritis and rheumatism; and the label statement "Active Ingredients: Calcium Succinate" was false and misleading since calcium succinate contributed nothing of therapeutic importance to the article.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient since the common or usual name of acetylsalicylic acid is aspirin.

DISPOSITION: March 19, 1953. Default decree of condemnation and destruction.

4054. Misbranding of Ar-Rhitis Capsulets. U. S. v. 63 Bottles * * *. (F. D. C. No. 34682. Sample No. 53196–L.)

LIBEL FILED: On or about March 3, 1953, Western District of Missouri.

ALLEGED SHIPMENT: On or about January 15, 1953, by the Reese Chemical Co., from Cleveland, Ohio.

PRODUCT: 63 bottles, each containing 72 *Ar-Rhitis Capsulets* at Springfield, Mo.

RESULTS OF INVESTIGATION: Two placards entitled "New Treatment for Pain Relief of Arthritis & Rheumatism" were shipped with the product. In addition a placard reading "Are You Troubled With Arthritis? Try This On A Money Back Guarantee, Ask For Details" was made up by the dealer for use in promoting the product and was displayed with it.

LABEL, IN PART: (Bottle) "Ar-Rhitis 72 Capsulets Each Contains: Sodium Salicylate . . . 4 grs. Para Amino Benzoic Acid . . . 5 grs. Ascorbic Acid (C) . . . 15 mgs. Thiamin Hydrochloride (B) . . . 3 mgs. * * * for the Relief of Minor Aches and Pains of Arthritis and Rheumatism."

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*See also Nos. 4041, 4046, 4048–4050, 4052.

NATURE OF CHARGE: Misbranding, Section 502 (a), the name of the product and certain statements appearing on the bottle label and on the accompanying placards were false and misleading. Such statements, together with the name of the product, represented and suggested that the article was an adequate and effective treatment for arthritis and rheumatism, whereas the article was not an adequate and effective treatment for such conditions. The article was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: April 1, 1953. Default decree of destruction.

4055. Misbranding of Kon-trol-R. U. S. v. 830 Cartoned Bottles, etc. (F. D. C. No. 34689. Sample No. 56942–L.)

LIBEL FILED: February 26, 1953, Southern District of Ohio.

ALLEGED SHIPMENT: On or about May 20, 1952, by the Kon-trol-R Co. of America, from Indianapolis, Ind.

PRODUCT: 830 cartoned bottles of *Kon-trol-R* at Cincinnati, Ohio, together with a number of circulars entitled "Kon-trol-R For Your Figure." The bottles were in ½-pint and 1-pint sizes. Examination showed that the product was mint-flavored cider vinegar.

LABEL, IN PART: (Bottle and carton) "Kon-trol-R For Your Figure * * * A Special Blend of Pure Apple Juice Processed for Optimum Acidity, Mint Flavored."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article and in the accompanying circular were false and misleading since the statements represented and suggested that the article was effective to bring about a loss of body weight, whereas the article was not effective for that purpose.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: April 20, 1953. Default decree of condemnation and destruction.

4056. Misbranding of Derma-Cura medicated skin cleanser. U. S. v. 24 Bottles * * *. (F. D. C. No. 34146. Sample No. 44343–L.)

LIBEL FILED: December 3, 1952, District of Rhode Island.

ALLEGED SHIPMENT: On or about August 28, 1952, by Derma-Cura Laboratories, from Worcester, Mass.

PRODUCT: 24 6-ounce bottles of *Derma-Cura medicated skin cleanser* at Woonsocket, R. I.

LABEL, IN PART: (Bottle) "Derma-Cura Medicated A Pore Deep Skin Cleanser * * * Contains camphor, boric acid, essential oils, alcohol 171 c. c. 6 fl. oz."

NATURE OF CHARGE: Misbranding, Section 502, (a), certain statements on the bottle label and in the circular entitled "Derma-Cura Medicated A Pore Deep Skin Cleanser for particular people" attached to each bottle were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for pyogenic skin infections, freeing clogged skin pores, and stimulating growth of new skin when old skin had been destroyed by infection, rendering the skin sterile and free from eruptions. The article was not an adequate and effective treatment for such conditions and purposes.

DISPOSITION: On December 23, 1952, "Respondent's Answer" was filed, which did not state or establish the name of any person or concern having an interest in the property under seizure. Moreover, no claim of ownership to establish an interest in the seized property was filed. In these circumstances, a motion was made on behalf of the Government for the entry of a decree of condemnation. On June 23, 1953, after consideration of the Government's motion, judgment of condemnation was entered and the court ordered that the product be destroyed.

4057. Misbranding of Radiant Ozone Generator. U. S. v. 1 Device, etc. (F. D. C. No. 34676. Sample No. 54761–L.)

LIBEL FILED: February 25, 1953, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about November 30, 1952, J. C. Gage, doing business as Wayside Health Home, Eldorado Springs, Mo., delivered to Oscar E. Buchanan 1 device and accompanying printed matter which then were transported by Mr. Buchanan from Eldorado Springs, Mo., to Alma, Mich.

PRODUCT: 1 *Radiant Ozone Generator* at Alma, Mich., together with a number of mimeographed direction sheets, a mimeographed sheet headed "Color," a number of mimeographed sheets of testimonials, and a mimeographed copy of an affidavit, dated November 21, 1947, and signed by J. C. Gage, referring to the testimonials.

The device consisted essentially of a series of tubes, which were similar to neon tubes, with connections for attachment to a source of electric current.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned printed matter accompanying the device were false and misleading. The statements represented and suggested that the device would give one health and strength and help one to get well, and that it constituted an adequate and effective means for the treatment of arthritis, angina, diphtheria, mumps, whooping cough, asthma, bladder and kidney trouble, blood disorders, anemia, cancer, diabetes, cataract, catarrh, heart trouble, hay fever, colds, sinus trouble, liver trouble, neuritis, piles, prostate gland affections, colitis, constipation, pneumonia fever, paralysis, rheumatism, ulcers, sores, sprains, varicose veins, tuberculosis, mastoid affections, earache caused by cold or injury, migraine headaches, stiff knee, stiff hip, stiff back, swollen leg, bronchial disturbances, low blood pressure, weakened, rundown condition, piles, bloat, throat trouble, bruise, diseases caused by impure blood and poor circulation, nervous breakdown, crippled knee, nervousness, inflammation of kidneys, blood clots, flu, soreness in the neck, prostate gland trouble, stomach trouble, paralysis, high blood pressure, enlarged heart, appendicitis, boils, poison oak, chickenpox, sciatic rheumatism, headaches, cramps in the leg, gland trouble, and "all diseases known to suffering humanity." The device would not give one health and strength or help one to get well, and it did not constitute an adequate and effective means for the treatment of the conditions stated and implied.

DISPOSITION: April 16, 1953. Default decree of condemnation. The court ordered that the device and the printed matter be delivered to the Food and Drug Administration.

4058. Misbranding of Radiant Ozone Generator. U. S. v. 1 Device, etc. (F. D. C. No. 34641. Sample No. 10079–L.)

LIBEL FILED: February 6, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about December 5, 1952, from Eldorado Springs, Mo., by and on behalf of J. C. Gage.

PRODUCT: 1 *Radiant Ozone Generator* at Milwaukee, Wis., together with a set of mimeographed direction sheets, a mimeographed sheet headed "Color," a number of mimeographed sheets of testimonials, and a mimeographed copy of an affidavit, dated November 27, 1947, and signed by J. C. Gage, referring to the testimonials.

The device consisted essentially of a series of tubes, which were similar to neon tubes, with connections for attachment to a source of electric current.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the above-mentioned mimeographed sheets and on the mimeographed copy of the affidavit accompanying the device were false and misleading. The statements represented and suggested that the device would give one health and strength and help one to get well, and that it constituted an adequate and effective means for the treatment of varicose veins, weakened, rundown condition, arthritis, sciatic rheumatism, cataract, headache, kidney trouble, asthma, anemia, colitis, sinus trouble, weak and nervous condition, hay fever, neuritis, chronic constipation, bronchial trouble, throat trouble, liver trouble, bruise, diabetes, low blood pressure, cold, cramps in the legs, stomach trouble, gland trouble, bloat, flu, pernicious anemia, appendicitis, impure blood, poor circulation, high blood pressure, enlarged heart, pleurisy, angina pectoris, pneumonia, sprains, neuralgia, blood clots, paralysis, catarrh of the nose and throat, sore throat, cuts, sores, backache, ear ailment, crippled knee, chickenpox, eczema, wen, loss of voice, broken ankle, piles, boil, poison oak, diphtheria, mumps, whooping cough, blood disorders, cancer, ulcers, tuberculosis, mastoid trouble, earache, heart trouble, prostate gland trouble, and "all diseases known to suffering humanity." The device was not capable of fulfilling the promises of benefit made for it, and it did not constitute an adequate and effective means of treating the conditions stated and implied.

DISPOSITION: May 7, 1953. Default decree of condemnation and destruction. On May 11, 1953, the decree was amended to provide for the delivery of the device and the accompanying literature, to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

4059. Misbranding of citrate of magnesia. U. S. v. 14 Cases * * *. (F. D. C. No. 34619. Sample No. 66998–L.)

LIBEL FILED: January 21, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about July 8, 1952, by the Philadelphia Magnesia Co., from Philadelphia, Pa.

PRODUCT: 14 cases, each containing 24 11½-ounce bottles, of *citrate of magnesia* at Camden, N. J.

LABEL, IN PART: (Bottle) "Penn Brand Pasteurized Effervescing Solution of Citrate of Magnesia U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (g), the article purported to be and was represented as "Magnesium Citrate Solution," a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not labeled as prescribed therein since it contained benzoic acid, a preservative, and the presence and proportion of such preservative was not plainly stated on the label, as required by the compendium.

DISPOSITION: March 20, 1953. Default decree of condemnation. The court ordered that the product be delivered to local hospitals.

4060. **Misbranding of first aid kits. U. S. v. 420 Kits * * *.** (F. D. C. No. 34076. Sample No. 14043–L.)

LIBEL FILED: October 2, 1952, District of Colorado.

ALLEGED SHIPMENT: On or about August 4, 1952, by A. E. Halperin Co., Inc., from Boston, Mass.

PRODUCT: 420 *first aid kits* at Remaco, Colo. Examination showed that in most units the glassine paper wrappers of the bandage compress component was not intact but was torn or split open exposing the compress to the air.

LABEL, IN PART: "First Aid Kit A. E. Halperin Co. Inc."

NATURE OF CHARGE: Misbranding Section 502 (g), the bandage compress component purported to be "Sterile Absorbent Gauze," an article recognized in the United States Pharmacopeia, but was not packaged as required by that compendium since it was not so packed that the sterility of the unit was maintained until the package was opened for use.

DISPOSITION: January 19, 1953. A. E. Halperin Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond, conditioned that it be sterilized and repackaged under the supervision of the Food and Drug Administration.

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PRODUCTS

[1] (4045, 4046) Injunction issued.

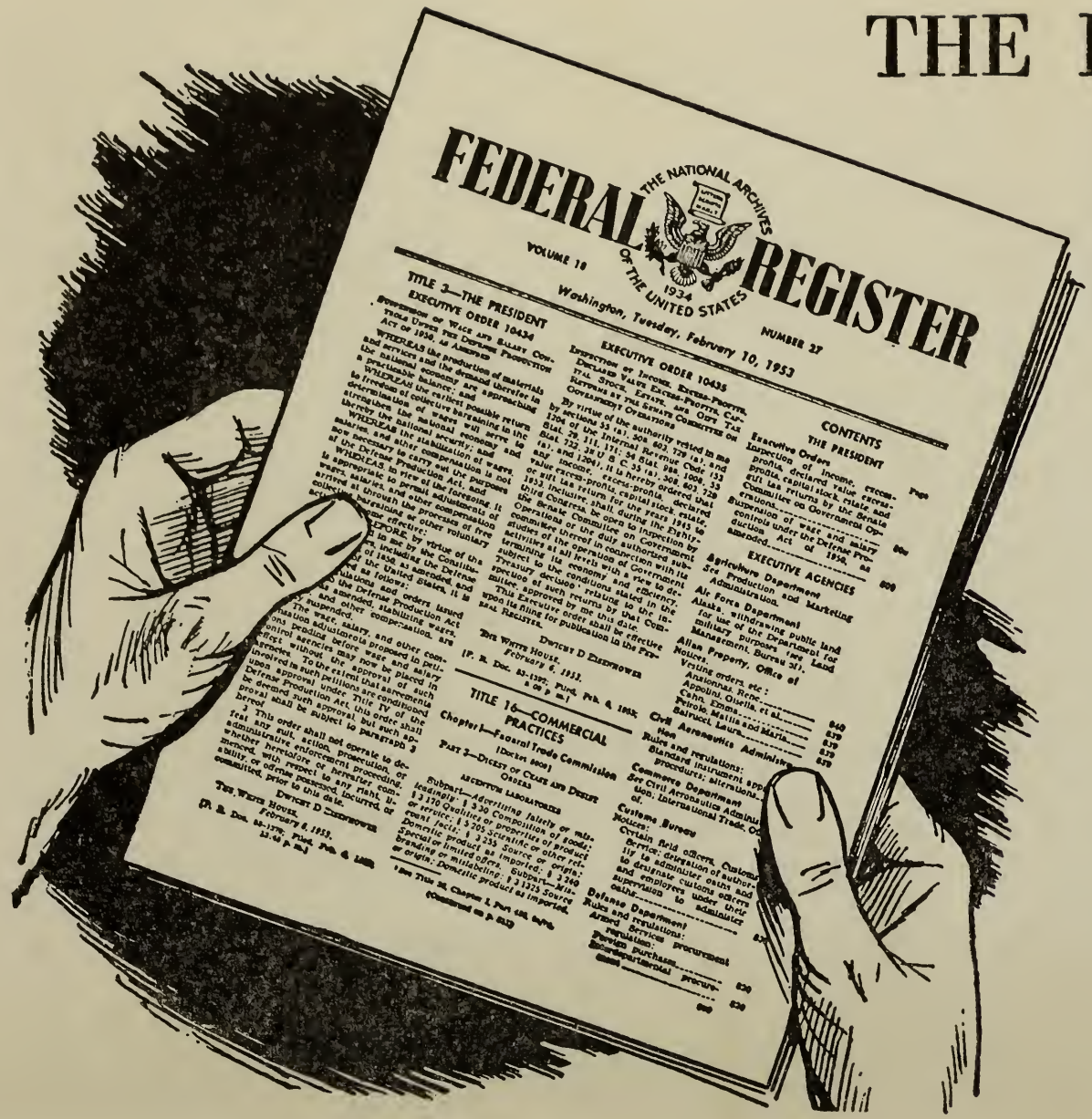
[2] (4047) Seizure contested. Contains findings of fact and conclusions of law.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4045, 4046) Injunction issued.
[2] (4047) Seizure contested. Contains findings of fact and conclusions of law.
[3] (4043) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1954

THE FEDERAL REGISTER



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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4061–4080

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 10, 1954.*

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286313—54——1

VIOLATIVE SALES OF PRESCRIPTION DRUG

4061. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Community Cash Drug Stores and Douglas S. Slocum and Vera D. Lamy. Pleas of nolo contendere. Fine of $200 against firm, $50 against Defendant Slocum, and $50 against Defendant Lamy. (F. D. C. No. 33848. Sample Nos. 46539–L to 46542–L, incl.)

INFORMATION FILED: December 5, 1952, Eastern District of Louisiana, against the Community Cash Drug Stores, a partnership, Baton Rouge, La., and Douglas S. Slocum and Vera D. Lamy, pharmacists for the partnership.

NATURE OF CHARGE: On or about July 9 and 10, 1952, while quantities of *dextro-amphetamine sulfate tablets* were being held for sale at Community Cash Drug Stores, after shipment in interstate commerce, the defendants caused various quantities of the tablets to be dispensed without prescriptions from practitioners licensed by law to administer such drugs. This dispensing was contrary to Section 503 (b) (1) and resulted in the tablets so dispensed being misbranded while held for sale.

DISPOSITION: June 24, 1953. Pleas of nolo contendere having been entered by the defendants, the court fined the partnership $200, Defendant Slocum $50, and Defendant Lamy $50.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4062. Misbranding of pentobarbital sodium capsules. U. S. v. David Young (Young's Pharmacy). Plea of guilty. Sentence of 1 year in jail and fine of $3,000. (F. D. C. No. 33799. Sample Nos. 6155–L, 6162–L, 6177–L, 6203–L, 6209–L.)

INFORMATION FILED: February 5, 1953, District of Massachusetts, against David Young, trading as Young's Pharmacy, Boston, Mass.

ALLEGED VIOLATION: On November 5, 6, 9, 10, and 12, 1951, while a number of *pentobarbital sodium capsules* were being held for sale at Young's Pharmacy, after shipment in interstate commerce, the defendant caused a number of the capsules to be dispensed without a physician's prescription, which act resulted in the capsules so dispensed being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the capsules which were dispensed failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the capsules which were dispensed failed to bear adequate directions for use.

DISPOSITION: Following the defendant's motion for a bill of particulars filed on March 3, 1953, the Government filed a bill of particulars. Thereafter, the defendant entered a plea of guilty, and on July 14, 1953, the court sentenced him to serve 1 year in jail and fined him $3,000.

4063. Misbranding of sulfadiazine tablets and dextro-amphetamine sulfate tablets. U. S. v. Ernest C. Buchanan (Lenoir Drug Co.). Plea of nolo contendere. Fine, $75. (F. D. C. No. 34366. Sample Nos. 4425–L, 4427–L, 4428–L.)

INFORMATION FILED: March 31, 1953, Eastern District of North Carolina, against Ernest C. Buchanan, trading as the Lenoir Drug Co., Kinston, N. C.

ALLEGED VIOLATION: On or about March 4 and April 23, 1952, while a number of *sulfadiazine tablets* and *dextro-amphetamine sulfate tablets* were being held for sale at the Lenoir Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Sections 502 (f) (1) and (2), the labeling of the repackaged drugs failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

Further misbranding, Section 502 (e) (1), the label of the repackaged *sulfadiazine tablets* failed to bear the common or usual name of the drug.

DISPOSITION: April 13, 1953. A plea of nolo contendere having been entered by the defendant, the court fined him $75.

4064. Misbranding of sulfadiazine tablets, pentobarbital sodium capsules, and dextro-amphetamine sulfate tablets. U. S. v. Alexander L. Hogan (Hogan's Pharmacy). Plea of nolo contendere. Fine, $75. (F. D. C. No. 34814. Sample Nos. 3535–L, 3537–L, 4439–L.)

INFORMATION FILED: March 31, 1953, Eastern District of North Carolina, against Alexander L. Hogan, trading as Hogan's Pharmacy, Kinston, N. C.

ALLEGED VIOLATION: On or about April 18 and 23, 1952, while a number of *sulfadiazine tablets*, *pentobarbital sodium capsules*, and *dextro-amphetamine sulfate tablets* were being held for sale at Hogan's Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of these drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tables* and *dextro-amphetamine sulfate tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 13, 1953. A plea of nolo contendere having been entered, the court fined the defendant $75.

4065. Misbranding of dextro-amphetamine sulfate tablets, conjugated estrogen tablets, phenobarbital tablets, tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfacetamide, and tablets containing a mixture of sulfadiazine and bicarbonate of soda. U. S. v. Jay L. Wilder Drug Co., Jay L. Wilder, William F. Fanning, and Elmer Modlin. Pleas of nolo contendere. Fine of $500 against company, $50 against Defendant Wilder, $100 against Defendant Fanning, and $100 against Defendant Modlin, plus costs. (F. D. C. No. 33717. Sample Nos. 30970–L, 31740–L, 34302–L, 34304–L, 34305–L.)

INFORMATION FILED: October 10, 1952, Western District of Missouri, against the Jay L. Wilder Drug Co., a corporation, Joplin, Mo., and against Jay L. Wilder, president, William F. Fanning, vice president, and Elmer Modlin, an employee of the corporation.

ALLEGED VIOLATION: On or about November 1 and 2, 1951, while a number of *dextro-amphetamine sulfate tablets, conjugated estrogen tablets, phenobarbital tablets, tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfacetamide*, and *tablets containing a mixture of sulfadiazine and bicarbonate of soda* were being held for sale at the Jay L. Wilder Drug Co., after shipment in interstate commerce, various quantities of the drugs were caused to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

The corporation was charged with causing the acts of repacking and dispensing of the drugs in each of the five counts of the information; Jay L. Wilder was charged with causing such acts of repacking and dispensing with respect to the *tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfacetamide;* William F. Fanning was similarly charged with respect to the *conjugated estrogen tablets* and the *phenobarbital tablets;* and Elmer Modlin was likewise charged with respect to the *dextro-amphetamine sulfate tablets* and the *tablets containing a mixture of sulfadiazine and bicarbonate of soda.*

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *dextro-amphetamine sulfate tablets, tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfacetamide*, and *tablets containing a mixture of sulfadiazine and bicarbonate of soda* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *conjugated estrogen tablets* failed to bear a label containing the common or usual name of the tablets; Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate tablets* and *tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfacetamide* failed to bear labels containing the common or usual name of

each active ingredient of the tablets; and, Section 502 (f) (2), the labeling of the repackaged *tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfacetamide* and *tablets containing a mixture of sulfadiazine and bicarbonate of soda* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 27, 1953. Pleas of nolo contendere having been entered, the court fined the corporation $500, Defendant Wilder $50, Defendant Fanning $100, and Defendant Modlin $100, plus costs.

4066. Misbranding of dextro-amphetamine sulfate tablets, thyroid tablets, methyltestosterone tablets, capsules containing a mixture of Seconal Sodium and Amytal Sodium, tablets containing a mixture of penicillin G potassium, sulfadiazine, sulfamerazine, and sulfamethazine, and tablets containing a mixture of mannitol hexanitrate and phenobarbital. U. S. v. Wayne A. Hughes (Hughes Drug Store). Plea of nolo contendere. Fine, $300. (F. D. C. No. 33743. Sample Nos. 31029–L, 31030–L, 34178–L, 34383–L to 34385–L, incl.)

INFORMATION FILED: January 19, 1953, Western District of Missouri, against Wayne A. Hughes, trading as the Hughes Drug Store, Aurora, Mo.

ALLEGED SHIPMENT: On or about March 20 and 21, 1952, while a number of the above-mentioned drugs were being held for sale at the Hughes Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *capsules containing a mixture of Seconal Sodium and Amytal Sodium* and the repackaged *tablets containing a mixture of penicillin G potassium, sulfadiazine, sulfamerazine, and sulfamethazine* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *capsules containing a mixture of Seconal Sodium and Amytal Sodium* and the repackaged *tablets containing a mixture of mannitol hexanitrate and phenobarbital* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of such repackaged drugs failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *capsules containing a mixture of Seconal Sodium and Amytal Sodium*, the repackaged *tablets containing a mixture of penicillin G potassium, sulfadiazine, sulfamerazine, and sulfamethazine*, and the repackaged *tablets containing a mixture of mannitol hexanitrate and phenobarbital* were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient of such drugs; and, Section 502 (f) (2), the repackaged *tablets containing a mixture of penicillin G potassium, sulfadiazine, sulfamerazine,*

and sulfamethazine failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 2, 1953. A plea of nolo contendere having been entered, the court fined the defendant $300.

4067. Misbranding of diethylstilbestrol tablets, dextro-amphetamine sulfate tablets, and capsules containing a mixture of pentobarbital and carbromal. U. S. v. Thomas Daniels. Plea of nolo contendere. Fine, $300. (F. D. C. No. 33744. Sample Nos. 31031–L, 31032–L, 31036–L, 31037–L, 32349–L, 34181–L.)

INFORMATION FILED: January 22, 1953, Western District of Missouri, against Thomas Daniels, a clerk employed at the Wooten Drug Co., Aurora, Mo.

ALLEGED VIOLATION: On or about March 20, 25, and 26, 1952, while a number of *diethylstilbestrol tablets, dextro-amphetamine sulfate tablets*, and *capsules containing a mixture of pentobarbital and carbromal* were being held for sale at the Wooten Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged capsules contained a mixture of carbromal, a hypnotic substance, and pentobarbital, a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such substance and derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (2), the label of the repackaged capsules failed to bear the common or usual name of each active ingredient of the capsules.

DISPOSITION: April 2, 1953. The defendant having entered a plea of nolo contendere, the court fined him $300.

4068. Misbranding of lozenges of Sulfonamets with Topicaine and dextro-amphetamine sulfate tablets. U. S. v. Henley C. Suddreth (Standard Drug Stores No. 2). Plea of nolo contendere. Fine, $75. (F. D. C. No. 34839. Sample Nos. 3522–L, 3530–L, 3532–L.)

INFORMATION FILED: March 31, 1953, Eastern District of North Carolina, against Henley C. Suddreth, trading as Standard Drug Stores No. 2, Kinston, N. C.

ALLEGED VIOLATION: On or about March 4 and April 23, 1952, while a number of lozenges of *Sulfonamets with Topicaine* and *dextro-amphetamine sulfate tablets* were being held for sale at Standard Drug Stores No. 2, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the packer or distributor and an accurate statement of the quantity of the contents; and, Sections 502 (f) (1) and (2), the labeling of the repackaged drugs failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

Further misbranding, Section 502 (e) (2), the repackaged lozenges of *Sulfonamets with Topicaine* failed to bear a label containing the common or usual name of each active ingredient of the drug.

DISPOSITION: April 13, 1953. The defendant having entered a plea of nolo contendere, the court fined him $75.

4069. Misbranding of Fosfarsinol, Cordial Matisura, and Sanqrinol. U. S. v. 70 Cartoned Bottles, etc. (F. D. C. No. 34645. Sample Nos. 50842–L to 50844–L, incl.)

LIBEL FILED: February 3, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about November 26 and December 3, 1952, by the American Tropical Remedy Co., from Santurce, P. R.

PRODUCTS: 70 cartoned bottles of *Fosfarsinol*, 70 cartoned bottles of *Cordial Matisura*, and 34 cartoned bottles of *Sanqrinol* at New York, N. Y.

LABEL, IN PART: (Carton) "Fosfarsinol * * * Contains Strychnine Glycerophosphate and Vitamin B_1 * * * Each adult dose, one tablespoonful (approximately 15 cc.) contains: Alcohol 13.3% Strychnine Glycerophosphate 0.001 Gm. Thiamine Hydrochloride (Vitamin B_1) 0.005 Gm. Arrhenal 0.010 Gm. Sodium Glycerophosphate 0.300 Gm. Calcium Glycerophosphate 0.130 Gm. Aromatic Vehicle, sufficient quantity to make volume. Fosfarsinol is prescribed by physicians in those conditions in which it is indicated by the therapeutic properties of the medicinal ingredients it contains"; "Cordial Matisura * * * (Formerly Matricura) Alcohol 15.7% * * * Each dose of the Matisura Cordial, one tablespoonful (approximately 15 c. c.) contains: Viburnum Prunifolium 0.50 Gm. Mitchella Repens 0.50 Gm. Aletris Farinosa 0.25 Gm. Alcohol 2.35 c. c. Vehicle, sufficient quantity to make 15 c. c. Cordial Matisura Exclusive Tonic For The Woman"; and "Sanqrinol * * * (Formerly Sangrinol) Alcohol 13.3% * * * Each adult dose, one tablespoonful (approximately 15 c. c.) contains: Iron and Ammonium Citrate 0.500 Gm. Sodium Glycerophosphate 0.500 Gm. Arrhenal 0.010 Gm. Strychnine Glycerophosphate 0.001 Gm. Alcohol 2 c. c. Vehicle, sufficient quantity to make 15 c. c. Sanqrinol is an hematinic prescribed by physicians in those conditions indicated by the therapeutical properties of the medicinal ingredients it contains * * * Warning: Contains Strychnine Do not exceed stated dose."

NATURE OF CHARGE: *Fosfarsinol* and *Sanqrinol*. Misbranding, Section 502 (e) (2), the articles were fabricated from two or more ingredients and their labels failed to bear the common or usual name of each active ingredient since "Arrhenal" is not the common or usual name of the active ingredient, methanearsonic acid, and the labels of the articles failed also to disclose that such ingredient was a derivative of arsenic; and, Section 502 (f) (2), the labelings of the articles failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner

and form, as are necessary for the protection of users since the use of the articles by elderly people, because of the content of strychnine, may be dangerous and their continued or prolonged use, because of the content of an arsenic preparation, may result in serious injury.

Fosfarinol. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling did not reveal the diseases, conditions, or purposes for which the article was to be used.

Cordial Matisura. Misbranding, Section 502 (a), the label statement (in English and Spanish) "Exclusive Tonic For The Woman" was false and misleading since the article was not effective as a tonic for women.

DISPOSITION: April 22, 1953. Default decree of condemnation and destruction.

4070. Misbranding of various drugs. U. S. v. Ples Griffin. Plea of guilty. Fine, $850. (F. D. C. No. 33761. Sample Nos. 30994–L, 31283–L, 32592–L, 32593–L, 33941–L, 33966–L, 34049–L, 34050–L, 34431–L to 34434–L, incl., 34455–L to 34458–L, incl., 34618–L.)

INFORMATION FILED: March 7, 1953, Western District of Kentucky, against Ples Griffin, La Center, Ky.

ALLEGED SHIPMENT: Between the approximate dates of November 27, 1951, and March 9, 1952, from the State of Kentucky into the States of Illinois, Missouri, and Tennessee, of quantities of drugs designated "B," "K," "P," and "Douch," and two unlabeled articles of drug.

PRODUCT: The articles designated "B," "K," and "P" were composed essentially of fragments of walnut bark suspended in water. The article designated "B" contained also small inconsequential proportions of inorganic matter, such as epsom salt and soda. The article designated "P" contained also from about 8 to 12 percent, epsom salt. The article marked "Douch" consisted essentially of a solution in water of approximately 0.7 percent of copper sulfate. One of the unlabeled articles consisted essentially of water in which was dissolved 0.3 percent of material extracted from plants, and the other unlabeled article consisted of water, plant extractive material, and a trace of berberine.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since the labeling failed to reveal the conditions for which the articles were to be used.

Further misbranding, Section 502 (f) (1), the labeling of the various articles failed to bear adequate directions for use in the treatment of the following diseases, symptoms, and conditions and for the following purposes, for which the articles were prescribed, recommended, and suggested orally by the defendant: ("B," "K," and "P" in combination with one another.) Thyroid trouble, overweight, high blood pressure, nervousness, tenseness, stiff, swollen, and painful joints in hips, legs, arms, and hands, arthritis, to get germs out of the blood, gallbladder attack, pains in the right side and right shoulder, vomiting, change of life, dizziness, low blood pressure, obesity, bump in the right abdominal region, diabetes, to build up the pancreas so that it would work as it is supposed to, severe menstrual flooding, paleness, irritability, abdominal pain, to prevent cancer, appendicitis, lump in the breast, impurities of the blood, skin eruptions, anemia, chronic pain in the back and stomach, kidney trouble, sciatic rheumatism, and gas attacks; ("B" and "K" in combination with each other) impurities of the blood, skin eruptions, and anemia; ("B," "K," "P," and "Douch" in combination with one another) cancer; ("B," "K," and unlabeled drug containing a trace of berberine in combination with one another) severe

menstrual flooding, paleness, irritability, abdominal pain, and to prevent cancer; ("B," "K," and "Douch" in combination with one another) cancer of the womb; and (unlabeled drug with 0.3 percent plant extractive material) nail puncture wound in the knee.

DISPOSITION: April 22, 1953. The defendant having entered a plea of guilty, the court fined him $850.

4071. Misbranding of Antuls tablets. U. S. v. 275 Bottles, etc. (F. D. C. No. 34631. Sample No. 54475–L.)

LIBEL FILED: January 26, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about October 20, 1952, by Antuls, a division of Lite Laboratories, from Chicago, Ill.

PRODUCT: 304 60-tablet bottles and 34 120-tablet bottles of *Antuls tablets* at Racine, Wis.

LABEL, IN PART: (Bottle) "60 [or 120] Tablets Antuls An Antacid Indicated for the temporary relief of excessive gastric acidity. Active Ingredients: Dried Aluminum Hydroxide Gel, Magnesium Trisilicate, Desiccated Duodenum Extract, Gastric Mucin. Also contains Chlorophyl. Distributed by Lite Laboratories, 3201 Lawrence Avenue, Chicago 25, Illinois."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of stomach ulcers, which was the condition for which the article was offered in advertising disseminated and sponsored by its distributor, Antuls, a division of Lite Laboratories.

DISPOSITION: March 13, 1953. Default decree of condemnation and destruction.

4072. Misbranding of alfalfa concentrate capsules. U. S. v. 8 Cartons, etc. (F. D. C. No. 34615. Sample No. 54368–L.)

LIBEL FILED: February 2, 1953, Northern District of Indiana.

ALLEGED SHIPMENT: On or about December 16, 1952, and January 7, 1953, by Rowell Laboratories, Inc., from Baudette, Minn.

PRODUCT: 8 cartons, each containing 10 packages and each package containing 10 100-capsule unlabeled bottles, of *alfalfa concentrate capsules*, and 152 100-capsule labeled bottles of the article at Portland, Ind.

RESULTS OF INVESTIGATION: A number of the unlabeled bottles which had been shipped in interstate commerce were labeled by the consignee, Alfalfa Concentrate, Inc., with labels which had been printed locally for the consignee.

LABEL, IN PART: (Package) "10 x 100 Capsules Special Formula No. 7180 * * * Each Capsule Contains: Alfalfa Extract . . . 5 grs." and (bottle) "100 Capsules ACC * * * Alfalfa Concentrate Capsules Suggested as an aid in the treatment of arthritis–rheumatism Each Capsule Contains As An Active Ingredient: Powdered Extract Alfalfa . . . 5 Grains One capsule 3 to 4 times each day. $4.89 Distributed By: Alfalfa Concentrate, Inc. 128 East Main Street Portland, Ind."

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents in terms of numerical count; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in those conditions for

which it was intended. The article was misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding (152-bottle lot), Section 502 (a), the labeling statement "Suggested as an aid in the treatment of arthritis–rheumatism" was false and misleading since the article was not effective in the treatment of arthritis and rheumatism. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: April 13, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4073. Adulteration and misbranding of C–Tone. U. S. v. 64 Bottles * * *. (F. D. C. No. 34373. Sample No. 23500–L.)

LIBEL FILED: December 4, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about June 21, 1951, by Kegan Laboratories, Inc., from Englewood, N. J.

PRODUCT: 64 8-ounce bottles of *C–Tone* at Jamaica, Long Island, N. Y. Analysis disclosed that the product contained approximately 24 percent of the declared amount of vitamin C and approximately 50 percent of the declared amount of niacin.

LABEL, IN PART: (Bottle) "C–Tone Natural Vitamin C Tonic."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 250 milligrams of vitamin C and 0.08 milligram of niacin in each 4 tablespoons. Misbranding, Section 502 (a), the label statement "4 tablespoons furnishes: Natural Vitamin C 250 mg. * * * Natural Niacin 0.08 mg." was false and misleading as applied to the article, which contained less than 250 milligrams of vitamin C and less than 0.08 milligram of niacin per 4 tablespoons. The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (a), the label statements "C–Tone rapidly builds up bodily stores of this essential vitamin, deficiency of which may contribute to many chronic ailments * * * to help reduce irritations in the stomach and intestinal tract" were false and misleading since the article was not effective to prevent and correct many chronic ailments or to reduce irritations in the stomach and intestinal tract. The article was misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: May 19, 1953. Default decree of condemnation and destruction.

4074. Adulteration and misbranding of isopropyl alcohol rubbing compound. U. S. v. 24 Cases * * *. (F. D. C. No. 34666. Sample No. 38913–L.)

LIBEL FILED: On or about February 26, 1953, Western District of Virginia.

ALLEGED SHIPMENT: On or about January 5, 1953, by the Best Sales Co., from Middlesboro, Ky.

PRODUCT: 24 cases, each containing 12 1-pint bottles, of *isopropyl alcohol rubbing compound* at St. Paul, Va.

LABEL, IN PART: (Bottle) "Best Rubbing Alcohol 70% Isopropyl Compound By Volume * * * Best Sales Co. Cincinnati, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Isopropyl Alcohol Rubbing Compound," a drug the

name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard. The standard provides that isopropyl alcohol rubbing compound contains not less than 68 percent and not more than 72 percent of isopropyl alcohol by volume, whereas the article contained from 36.5 percent to 100 percent of isopropyl alcohol by volume.

Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear an accurate statement of the proportion of alcohol contained therein.

DISPOSITION: April 14, 1953. Default decree of condemnation and destruction.

4075. Adulteration and misbranding of clinical thermometers. U. S. v. 408 Thermometers * * *. (F. D. C. No. 34392. Sample No. 40625–L.)

LIBEL FILED: December 11, 1952, Western District of Washington.

ALLEGED SHIPMENT: On or about October 10, 1952, by the Dependable Thermometer Co., from New York, N. Y.

PRODUCT: 408 *clinical thermometers* at Seattle, Wash. Examination of 24 thermometers showed that 4 failed to meet the test for accuracy, that 2 failed to meet the test for retreating index, and that 1 was a hard shaker.

LABEL, IN PART: "Dependable Oral."

NATURE OF CHARGE: Aduleration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to the article, which failed to meet the tests laid down in Commercial Standard CS1–52, issued by the United States Department of Commerce, for accuracy, retreating index, and hard shaker: (Brown envelope in which each thermometer is packaged) "Certificate and Guarantee of Accuracy and Reliability * * * Oral This Registering Clinical Thermometer was tested and examined on the above date and was found to meet all of the requirements and tests specified in Commercial Standard CS1–52, developed by the trade under the procedure of the Commodity Standards Division and issued by the United States Department of Commerce."

DISPOSITION: May 18, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4076. Misbranding of Duodex capsules. U. S. v. 36 Dozen Bottles, etc. (F. D. C. No. 33291. Sample No. 38740–L.)

LIBEL FILED: June 9, 1952, District of Columbia; libel amended June 4, 1953.

ALLEGED SHIPMENT: On or about June 2, 1952, by Harris Laboratories, Inc., from Glen Cove, N. Y.

PRODUCT: *Duodex capsules.* 36 dozen bottles, each containing 100 capsules, and 60 dozen bottles, each containing 50 capsules, at Washington, D. C., together with a number of leaflets entitled "Duodex The New Effective Treatment For Peptic and Duodenal Ulcer Sufferers," "At Last A Cure For Ulcers," and "The New Ulcer Story," a number of window streamers entitled "Come In For Free Booklet," and a number of display placards entitled "Stomach Ulcer Pains."

*See also Nos. 4069, 4072, 4073, 4075

LABEL, IN PART: (Bottle) "Duodex * * * each capsule contains approximately 0.3 grams of desiccated and partially defatted duodenal substance processed to retain the ingredients believed to relieve ulcer pains and symptoms of ulcerative colitis."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were misleading since they represented and suggested that the article was an adequate and appropriate treatment for relief of stomach ulcer pains and symptoms of ulcerative colitis, indigestion, gastritis and similar conditions, duodenal ulcer pains, and for peptic and duodenal ulcer sufferers, whereas such was not the case.

Further misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article would not be effective for the purposes stated and implied: (Leaflet entitled "Duodex The New Effective Treatment for Peptic and Duodenal Ulcer Sufferers") "Duodex, the new effective treatment for peptic and duodenal ulcer sufferers * * * Duodex acts as replacement therapy restoring to the mucosal surface that essential substance present in normal duodenum, that aids in healing the ulcer crater and restores a normal intestinal lining * * * It has been suggested that * * * Duodex provides * * * substances needed by nature to aid her in rebuilding the normal mucosal lining and smooth over the raw, eroded ulcer surface. Duodex * * * may repair the ulcerated area * * * Duodex is a valuable adjunct to aid in relieving this prevalent disease of modern strife and turmoil * * * Duodex * * * is today's ulcer therapy of choice * * * I have * * * used * * * Duodex Capsules * * * I have suffered from ulcers for 8 years and at last I can eat and sleep and I feel like a new man * * * Your capsules have worked * * *." and "Your Duodex Capsules have done so much for me that I feel as though I have never had any stomach ailment"; (leaflet entitled "At Last A Cure For Ulcers") "At Last A Cure For Ulcers? * * * Duodenum It may well be magic medicine for a painful disorder. You've got a stomach ulcer * * * Old Man Ulcer takes his added toll of fast-tempoed emotionally-upset 20th century citizens * * * I'm talking about myself. For seven years I was an expert on stomach ulcer misery * * * Now it's all over. My ulcer's just an unhappy memory. I have no pain. I have no discomfort * * * the real answer to peptic ulcer and ulcerative colitis * * * hog's duodenum * * * knocked out ulcer symptoms within 24 to 48 hours, kayoed the ulcer itself in a matter of weeks * * * Duodenum had been remarkably successful in more than 300 clinical cases, with no failures * * * restored a woman colitis victim on the verge of death to health within a month * * * my ulcer hemorrhaged * * * it was almost an inch deep, dangerously near a main artery * * * I began taking Duodenum, along with a liberal diet and amino acids * * * Two weeks later the ulcer crater had more than half healed * * * Was Duodenum mainly responsible? I feel it was. Never before have I been so free of pain, felt better physically and sharper mentally * * * 'Good-by, my aching ulcer' * * * I have * * * used * * * Duodex Capsules * * * I have suffered from ulcers for 8 years and at last I can eat and sleep and I feel like a new man * * * Your capsules have worked * * *." and "Your Duodex Capsules have done so much for me that I feel as though I have never had any stomach ailment."

Further misbranding (amended libel), Section 502 (a), the statements upon the counter display card "Tested in Leading Medical Centers for more than a year with remarkable results * * * Over 300 clinical cases with no failures—An Amazing Achievement" were false and misleading since such statements

represented and suggested that the article had been so tested, whereas such was not the case.

DISPOSITION: On October 28, 1952, Harris Laboratories, Inc., claimant, filed an answer denying that the product was misbranded. Interrogatories then were served upon the claimant by the Government, after which answers to certain interrogatories were filed by the claimant, together with objections to the remainder of the interrogatories. A motion for removal of the libel proceedings for trial in the Southern District of New York was filed also by the claimant. On April 4, 1953, the court denied the claimant's motion for removal, and on April 13, 1953, the court held a hearing on the interrogatories and ruled that the claimant should fully and completely answer certain interrogatories, but that it need not answer the remainder of the interrogatories.

On June 4, 1953, upon motion of the Government, the libel was amended to include the additional misbranding charge described above. Thereafter, the Government filed a motion for summary judgment, and on August 24, 1953, after hearing the argument on the motion and considering the labeling and the answers to the interrogatories, the court concluded that there existed no genuine issue as to any material fact. Accordingly, the court granted the Government's motion and entered a decree of condemnation and destruction.

4077. Alleged misbranding of Ridd medicated powder. U. S. v. 52 Cases * * *. Motions for removal denied. Tried to the court; verdict for the Government. Decree of condemnation. Judgment reversed upon appeal. Action subsequently dismissed. (F. D. C. No. 33105. Sample No. 22304–L)

LIBEL FILED: May 6, 1952, Northern District of Texas.

ALLEGED SHIPMENT: On or about February 18, 1952, by Ridd Laboratories, Inc., from Edmonds, Wash.

PRODUCT: 52 cases, each containing 144 1-ounce bottles, of *Ridd medicated powder* at Dallas, Tex. Analysis showed that the product was boric acid with a small amount of iodine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and display carton of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for skin troubles, pimples, acne, barber's itch and skin itch, skin rash, ringworm, fungus, industrial skin irritations, boils, and varicose ulcers, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: Ridd Laboratories, Inc., claimant, filed an answer denying that the product was misbranded, and on May 27, 1952, it filed a motion for removal of the libel proceedings to the Western District of Washington. The court denied the motion on June 3, 1952, after which the claimant moved for removal to a district of reasonable proximity to the claimant's principal place of business.

This motion was denied on June 9, 1952, and the case came on for trial before the court without a jury on June 13, 1952. At the conclusion of the testimony, the court returned a verdict for the Government, and on June 16, 1952, entered a decree of condemnation and destruction. The claimant took an appeal to the United States Court of Appeals for the Fifth Circuit, and on April 2, 1953, the following opinion was handed down by that court:

HUTCHESON, *Chief Judge:* "This is an appeal from a judgment of condemnation and forfeiture entered pursuant to a libel charging misbranding under Sec. 301 et seq of the Federal Food, Drug, and Cosmetic Act.[1] Bringing them up for our review, claimant below, appellant here, makes serious complaint of three adverse rulings of the district judge, including his finding that the powder was misbranded.

"The primary one of the rulings and the one of which appellant makes vigorous complaint is the denial by the district judge of appellant's motion filed under Sec. 334 (a),[2] 21 U. S. C. A., to remove and transfer the cause.

"If the district judge had a discretion to refuse to remove the cause, and we do not think he had because the statute provides that the court 'shall by order unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial,' we think he abused that discretion here. For no good cause to the contrary was shown.

"While it is quite plain that the district judge thought that he was acting in accordance with the statute, it is equally plain that he was laboring under a mistaken opinion as to its provisions and effect.

"In view of the fact that, because of the error in denying removal of the cause, the judgment must be reversed, it is unnecessary, indeed inappropriate, for us to canvass and discuss the other errors assigned.

"For the error, therefore, of denying removal of the cause, the judgment is reversed and the cause is remanded to the district court with directions to 'specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.'

"REVERSED and REMANDED with directions."

In accordance with the above opinion, the case was ordered transferred from the Northern District of Texas to the Eastern District of Washington. On October 5, 1953, the United States District Court for the Eastern District of Washington ordered that the libel action be dismissed since it appeared that the product under seizure had been inadvertently destroyed.

4078. Misbranding of Muscle-Rub. U. S. v. 1 Lot, etc. (F. D. C. No. 32468. Sample Nos. 427–L to 429–L, incl.)

LIBEL FILED: January 30, 1952, Western District of Texas.

ALLEGED SHIPMENT: On or about December 1, 1951, by Muscle-Rub Distributors, from Los Angeles, Calif.

PRODUCT: 1 lot of *Muscle-Rub* consisting of 8 dozen 2-ounce bottles, 33⅓ dozen 6-ounce bottles, and 6 dozen 12-ounce bottles at El Paso, Tex. A leaflet containing statements relating to the product was attached to each bottle.

RESULTS OF INVESTIGATION: To establish the setting in which the labeling statements would be read by the consumer, Muscle-Rub Distributors supplied advertising mats for advertising in various editions of the El Paso newspapers, which pictured for contrast a gnarled, deformed hand of a person suffering from arthritis deformans and a hand in normal condition and which contained the statement in bold type "Rheumatism Arthritis Pains Relieved in a few minutes with Doctor's External Prescription," followed by statements and testimonials relating to the efficacy of the product.

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[1] 21 U. S. C. A., Sec. 321 et seq.

[2] As pertinent here the article provides:
"* * * In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial."

LABEL, IN PART: (Bottle) "Use as an aid in the Relief of Pain and Discomfort from Rheumatism, Arthritis, Neuralgia, Sciatica, & Sprains * * * Muscle-Rub": (leaflet attached to bottle) "Muscle-Rub A Glorious Aid in the Relief of Pain and Discomfort from Rheumatism, Arthritis, Neuralgia, Sciatica, Sprains * * * Bruises."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was false and misleading because when read in the light of the setting in which it was intended to be read, it conveyed to the public a meaning which represented and suggested that the article was more than a palliative relief for simple muscular pains and was an adequate and effective treatment for rheumatism, arthritis, neuralgia, sciatica, sprains, and bruises, whereas the article was not an adequate and effective treatment for rheumatism, arthritis, neuralgia, sciatica, sprains, and bruises.

DISPOSITION: On February 16, 1952, upon motion of Pauline Harrison, trading as Muscle-Rub Distributors, the claimant, and with the consent of the Government's attorney, an order was entered by the court consolidating for trial the instant case with that reported in the following notice of judgment, No. 4079, and directing that the consolidated cases be removed for trial to the United States District Court for the District of Arizona. The claimant thereafter withdrew her claim, and, on June 3, 1953, the court entered a decree of condemnation and destruction.

4079. Misbranding of Muscle-Rub. U. S. v. 405 Bottles, etc. (F. D. C. No. 32214. Sample Nos. 13274–L, 13275–L.)

LIBEL FILED: December 3, 1951, Western District of Texas.

ALLEGED SHIPMENT: On or about December 7, 1950, and October 20, 1951, by Muscle-Rub Distributors, from Los Angeles, Calif.

PRODUCT: 322 6-ounce bottles and 83 12-ounce bottles of *Muscle-Rub* at El Paso, Tex., together with a leaflet entitled "Muscle-Rub" attached to each bottle of the product and an accompanying placard entitled "Prove Free" relating to the product.

LABEL, IN PART: (Bottle) "Muscle-Rub Contains Isopropyl Alcohol 75% Ethyl Alcohol 1.8%, Methyl Salicylate, Camphor, Menthol & Fld. Ext. Witch Hazel."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label, in the above-mentioned leaflet, and on the above-mentioned placard were false and misleading in that the statements represented and suggested that the article was an adequate and effective treatment for arthritis, rheumatism, neuralgia, sciatica, neuritis, lumbago, swollen, aching joints, sprains, and bruises, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: On February 16, 1952, upon motion of Pauline Harrison, trading as Muscle-Rub Distributors, the claimant, and with the consent of the Government's attorney, an order was entered by the court consolidating for trial the instant case with that reported in the preceding notice of judgment, No. 4078, and directing that the consolidated cases be removed for trial to the United States District Court for the District of Arizona. The claimant thereafter withdrew her claim, and, on June 3, 1953, the court entered a decree of condemnation and destruction.

4080. Misbranding of Fresh'nd-Aire humidifier. U. S. v. 26 Devices, etc. (F. D. C. No. 34442. Sample No. 54460–L.)

LIBEL FILED: December 17, 1952, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about October 22 and 30, 1952, by the Fresh'nd-Aire Co., Division of Cory Corp., from Chicago, Ill.

PRODUCT: 26 *Fresh'nd-Aire humidifiers* at Milwaukee, Wis., together with a number of leaflets entitled "How It Works" and "The Exciting New Fresh'nd-Aire Humidifier!"

The humidifier consisted of a tank which would hold 6 quarts of water and contained a fan which when plugged into the house electric line, would force air from the room to pass through a moistened filter pad. A small pump was incorporated in the device to circulate water over the filter pad, and thus keep it moist.

LABEL, IN PART: (Device) "Fresh'nd-Aire Humidifier Model 700 * * * 60 Cycles 30 Watts"; (tag) "America's Newest Health Appliance Fresh'nd-Aire."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets which accompanied the devices were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for preventing coughs, colds, dry, cracked skin, respiratory ailments, stopped-up nose, difficult breathing, dry, drawn skin, hay fever, and asthma, whereas the device would not provide an adequate and effective treatment for preventing such conditions.

DISPOSITION: May 19, 1953. The Fresh'nd-Aire Co., Division of Cory Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond to be brought into compliance with the law, under the supervision of the Department of Health, Education, and Welfare. The devices were relabeled.

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PRODUCTS

[1] (4076) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4076) Seizure contested.
[2] (4077) Seizure contested. Contains opinion of the court.

[2] (4077) Seizure contested. Contains opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1954

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4081–4100

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 22, 1954.*

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* For presence of a habit-forming narcotic without warning statement, see Nos. 4085, 4087; omission of, or unsatisfactory, ingredients statements, Nos. 4083, 4085, 4087; sale under name of another drug, No. 4084; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4083, 4085–4087; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4083, 4086, 4087.

291251—54——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4081. Misbranding of Benzedrine Sulfate tablets and Dexedrine Sulfate tablets. U. S. v. James Hendelberg. Plea of guilty. Fine of $1,000 or sentence of 60 days in jail. (F. D. C. No. 33752. Sample Nos. 3005–L, 3006–L.)

INFORMATION FILED: November 20, 1952, District of Columbia, against James Hendelberg, Washington, D. C.

NATURE OF CHARGE: On or about September 27, 1952, the defendant unlawfully sold, within the District of Columbia, certain dangerous, harmful, or toxic drugs without a physician's prescription, namely, *Dexedrine Sulfate tablets* and *Benzedrine Sulfate tablets*. Such acts of sale were in violation of Section 503 (b) (1) and resulted in the drugs being misbranded.

DISPOSITION: December 9, 1952. The defendant having entered a plea of guilty, the court sentenced him to serve 60 days in jail or, in the alternative, to pay a fine of $1,000.

4082. Misbranding of dextro-amphetamine sulfate tablets, sulfadiazine tablets, and Neotrizine tablets. U. S. v. Professional Pharmacy, Inc., and Patrick J. Santangelo. Plea of guilty by corporation to all 12 counts of information; plea of guilty by individual defendant to counts 7 and 9. Corporation fined $600. Individual defendant fined $250 on count 9; imposition of sentence on count 7 against individual suspended and this defendant placed on probation for 2 years. (F. D. C. No. 34304. Sample Nos. 24190–L, 36969–L, 36974–L, 36977–L, 37334–L, 37335–L, 37340–L, 37341–L, 37699–L, 37892–L, 37894–L, 37899–L.)

INFORMATION FILED: March 4, 1953, District of New Jersey, against Professional Pharmacy, Inc., Red Bank, N. J., and Patrick J. Santangelo, manager of the corporation.

NATURE OF CHARGE: On or about May 6, 13, 16, 20, 22, 27, and 28, 1952, while quantities of *dextro-amphetamine sulfate tablets*, *sulfadiazine tablets*, and *Neotrizine tablets* were being held for sale at Professional Pharmacy, Inc., after shipment in interstate commerce, the corporation caused various quantities of the drugs to be dispensed upon request for refills of written prescriptions, without obtaining authorization by the prescribing physician. Patrick J. Santangelo was joined as a defendant in counts 7 and 9 of the information, relating to the dispensing of a number of *Neotrizine tablets* and *dextro-amphetamine sulfate tablets*. The dispensing of the drugs involved was contrary to Section 503 (b) (1) and resulted in the drugs so dispensed being misbranded while held for sale.

DISPOSITION: May 4, 1953. The corporation entered a plea of guilty to each of the 12 counts of the information, and the individual entered a plea of guilty to counts 7 and 9. The court fined the corporation $50 on each of the 12 counts, or a total of $600, and fined the individual $250 on count 9. The court also suspended the imposition of sentence against the individual on count 7 and placed him on probation for 2 years.

4083. Misbranding of dextro-amphetamine sulfate tablets, methyltestosterone tablets, and tablets containing a mixture of sulfadiazine and sulfathiazole. U. S. v. Times Square Drug and Albert Kline. Pleas of guilty. Fine of $150 against each defendant. (F. D. C. No. 34334. Sample Nos. 36096–L, 36204–L, 36227–L.)

INFORMATION FILED: February 20, 1953, Northern District of Ohio, against Times Square Drug, a partnership, Cleveland, Ohio, and Albert Kline, a pharmacist for the partnership.

NATURE OF CHARGE: On or about April 10, 1952, while a number of *tablets containing a mixture of sulfadiazine and sulfathiazole* were being held for sale at Times Square Drug after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and dispensed without a prescription, which acts resulted in the repackaged tablets being misbranded as follows: Section 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the label of the repackaged tablets failed to bear the common or usual name of each active ingredient of the tablets; and, Section 502 (f) (1) and (2), the labeling of the repackaged tablets failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of the users.

On or about May 15 and June 11, 1952, while a number of *dextro-amphetamine sulfate tablets* and *methyltestosterone tablets* were being held for sale at Times Square Drug after shipment in interstate commerce, the defendants caused quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: March 13, 1953. Pleas of guilty having been entered, the court fined each defendant $150.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4084. Misbranding of homeopathic drugs. U. S. v. Various Quantities, etc. (F. D. C. No. 34103. Sample Nos. 64024–L to 64054–L, incl.)

LIBEL FILED: November 4, 1952, Western District of Washington.

ALLEGED SHIPMENT: On various dates, the Kansas City Homeopathic Pharmacy shipped from Kansas City, Mo., a number of drugs in tablet form in 5-pound packages. In addition, there were shipped by another firm, on July 25, 1952, and on other dates, from St. Louis, Mo., a number of drugs in powder form in labeled bulk containers. There was shipped also from a point outside of the State of Washington, on an unknown date, a quantity of a drug in powder form in an unlabeled bulk container.

PRODUCT: Various quantities of various homeopathic drugs in tablet form, some in 5-pound bulk packages in which they were shipped, and some in bottles of 400 tablets each into which the tablets were repacked from the bulk packages at destination; various quantities of drugs in powder form in labeled bulk containers and in retail-sized containers used in repacking such drugs; and a

quantity of a drug in powder form, some of which was in bulk in an unlabeled container and some of which had been repacked into retail-sized containers.

All of the drugs were in possession of L. W. Andrus, at Chehalis, Wash., together with a number of booklets entitled "Schuessler's Biochemic Remedies," a number of mimeographed sheets entitled "ABC Health Club Remedial Biochemistry," and a number of leaflets entitled "The most effective program." The booklets had been shipped to L. W. Andrus on September 15, 1952, and the mimeographed sheets and leaflets were prepared by or for L. W. Andrus and contained statements relating to the drugs in tablet form.

LABEL, IN PART: (Drugs in tablet form in bulk packages) "Homeopathic Calcarea Fluorica 3X Calcium Fluoride [or "Calcarea Phosphorica 3X Calcium Phosphate," "Calcarea Sulph. 3X Calcarea Sulphate," "Ferrum Phosphoricum 3X Iron Phospate," "Kali Muriaticum 3X Potassium Chloridum," "Kali Phosphoricum 3X Potassium Phosphate," "Kali Sulphuricum 3X Potassium Sulphate," "Magnesium Phosphorica 3X Magnesium Phosphate," "Natrum Muriaticum 3X Chloride of Sodium-Salt," "Natrum Phosphoricum 3X Sodium Phosphate," "Natrum Sulphuricum 3X Sodium Sulphate," and "Silicea 3X Silica"]."

(Drugs in tablet form repackaged into bottles) "Biochemic Remedies * * * 400 Tabs. 3X * * * L. W. Andrus, Oroville, Wash." and respectively identified as "Calcium Fluoride 1," "Calcium Phosphate 2," "Calcium Sulphate 3," "Iron Phosphate 4," "Potassium Chloride 5," "Potassium Phosphate 6," "Potassium Sulphate 7," "Magnesium Phosphate 8," "Sodium Chloride 9," "Sodium Phosphate 10," "Sodium Sulphate 11," and "Silica 12."

(Drugs in powder form in bulk containers) "Sodium Phosphate," "Sodium Sulphate," and "Calcium Phosphate."

(Drugs in powder form—repackaged) "Sodium (10 crude) Phosphate," "Sodium crude (11) Sulphate," and "Calcium (2 crude) Phosphate."

(Drug in powder form repacked from unlabeled container into retail-sized containers) "ABCO."

NATURE OF CHARGE: Drugs in tablet form (in bulk packages and as repacked into bottles). Misbranding, Section 503 (b) (4), the articles were drugs intended for use by man, which, because of the collateral measures necessary for their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." Further misbranding, Section 502 (a), the labeling of the articles in tablet form, namely, the accompanying booklet entitled "Schuessler's Biochemic Remedies," contained statements which were false and misleading in that the articles were not effective for the purposes stated and implied and were not capable of fulfilling the promises of benefit made for them. The statements represented and suggested—

(a) that all of the articles were effective to eliminate the cause of disease and restore health, and that they were effective for acute and chronic conditions;

(b) that the calcium fluoride was effective for the alleviation of affections of the respiratory organs and difficult expectoration, ulceration of mouth and throat, caries and necrosis with boring pains and heat in parts, induration threatening suppuration, chronic suppuration of middle ear, ailments arising from relaxed condition of the elastic fibers of the connective tissue or lymphatics, ailments caused by dilation of the blood vessels, such as simple hemorrhoids, blood tumors, prolapsus of the womb, swellings, indurated en-

largements, varicose and enlarged veins, hardened glands in female breast, glandular tumors, relaxed vulva, malnutrition of bones, acute indigestion from fatigue and brain fag, and much flatulence;

(c) that the calcium phosphate was effective for disturbances resulting from faulty nutrition or improper assimilation, such as simple anemia; for children who are peevish, flabby, have cold extremities, and feeble digestion; for delayed nutrition; for deficient development of children; for emaciation without apparent cause, as evidenced by spinal weakness, spinal curvature, "ruchiatis," craniotabes, and hydrocephalus; for suppuration of bones; to aid the union of fractured bones and promote the development of teeth; for the expectant mother, preserving her teeth and insuring proper development of her teeth; for individuals having green, slimy, hot, sputtering undigested stools, with fetid flatus; and to aid in chronic, wasting diseases;

(d) that the calcarea sulphate was effective to promote healing of simple skin eruptions, for the suppurative stage of skin and eruptive diseases; abscesses, boils, pustules, ulcers, burns or scalds, milk crust, ulcerated tooth; discharge of matter from ear, expectoration of pus, chronic catarrhal conditions with foul secretions, quinsy, sore throat, ulceration of glands, ulcers on legs, rattling coughs after colds, burning-itching of soles of feet, mucous discharges yellow, thick, and lumpy, and pimples and pustules on the face;

(e) that the iron phosphate was effective for the alleviation of the fever, congestion, inflammation, and pain occurring during the initial stage of minor acute ailments, such as colds, throat irritations, hard, dry, tickling cough after colds, flushed face, quick, full pulse, hot dry skin, thirst, marked prostration, pain and redness of the parts, first state of inflammation of any organ or tissue, simple anemia, muscular pains, vomiting of undigested food, incontinence, enuresis, with weak sphincter, epistaxis, bright red hemorrhages from any orifice, and congestive headaches;

(f) that the potassium chloride was effective for alleviation of catarrhal conditions, especially of the respiratory passages, thick white or grayish secretions from any of the mucous membranes, white or gray coating of the tongue, for the second stage of inflammatory diseases, subacute inflammatory states, fibrinous exudations and glandular swellings, skin affections of any part of the body, skin eruptions with small vesicles, containing yellowish secretions, leucorrhea, with mucus, sometimes yellowish, muscular pains with indigestion caused by fatty, rich food, and for coughs following colds;

(g) that the potassium phosphate was effective for the relief of minor disturbances of the nervous system, neurasthenic conditions in general prostration, irritability, restlessness, nervousness, sleeplessness, nervous headaches, neuralgic pains, lancinating pains in the nerves, enuresis, incontinence of urine, nervous dispepsia, dizziness, vertigo from nervous exhaustion, offensive, carrion-like diarrhea, predisposition to epistaxis in children, tongue as if spread with liquid (dark) mustard, offensive breath, humming and buzzing in the ears, very yellowish urine, and yellow expectoration;

(h) that the potassium sulfate was effective for the alleviation of inflammatory and catarrhal conditions with thin, sticky, watery, or slimy yellowish secretions with a yellow slimy deposit on tongue, coughing spells with oppressed breathing, hard, hoarse, or croupy cough with rattling of mucus in the chest, for skin diseases having a sticky, yellowish secretion and peeling off of the epidermis, for bronchitis, with yellow, slimy, or thin, watery expectoration, dyspepsia, catarrh of the stomach and bowels, with characteristic yellowish slimy coating of the tongue, catarrhal condition of bowels, ulceration or sud-

den suppression or retrocession of eruptions, and shifting, wandering pains in extremities;

(i) that the magnesium phosphate was effective as an antispasmodic, for the relief of spasmodic, muscular, and neuralgic pains, neuralgic headaches, cramps, facial neuralgia, pains in the head, face, teeth, stomach, and abdomen which are relieved by warmth, spasmodic retention of urine, spasmodic palpitation and cardiac pain while sitting, functional cardiac affections with liver enlargement, pains that are lightning-like, boring, shooting, change their location frequently; acute, loud, spasmodic coughs; and diseases having their origin in the nerve cells or in the terminal bulbs of the nerves, in the muscular tissues, or in the muscles themselves;

(j) that the chloride of sodium-salt was effective to alleviate the acute symptoms in colds, throat and bronchial irritations, hay fever with profuse, thin, watery vomiting, hypersecretion of the watery elements of the body with simultaneous lack in activity in some other portion of the mucous membrane, muscles weak and stiff, great weakness and weariness, coldness of legs with congestion in head, chest, and stomach, emaciation most notable in neck, great liability to take cold, dry mucous membranes, diseases of the respiratory organs, with thin, watery expectoration, headache, toothache, face ache, stomach ache, etc., where there is either salivation or hypersecretion of tears or vomiting of water and mucus, constipation, intermitting or remitting fever, catarrhal affections of mucous membranes with secretion of transparent, watery, frothy mucus, small watery blisters, breaking or leaving a thin crust, enuresis, diarrhea, transparent, glossy, slim stools, conjunctivitis with discharge of tears and clear mucus, loss of smell and taste, and leucorrhea with watery, smarting, or clear, starch-like discharges;

(k) that the sodium phosphate was effective for the relief of minor ailments characterized by gastric and excessive acidity of the stomach, sour eructations and taste, sour vomiting, chronic dyspepsia, flatulence with sour risings, heartburn, burning in stomach after meals, indigestion, sour smelling diarrhea, colic and spasms, yellow, creamy coating of the tongue, such as in diarrhea, acid stomach, muscular pains due to acidity, moist, thick, golden yellow, or creamy coating at the back of roof of mouth and tongue, ague with described coating of tongue, and eyes discharging a yellow, creamy water;

(l) that the sodium sulfate was effective for the alleviation of bilious and periodic headaches, colds, colic, diarrhea and disordered stomach with bilious symptoms, dark-coated tongue, bitter taste with excess of bile, hepatic derangements, enlargement of the liver, skin affections with bilious vomiting, yellowish skin, and moist, yellowish scales, every spring return of skin affections, and vomiting of pregnancy, with symptoms usually worse in the evening;

(m) that the silica was effective for the alleviation of minor skin ailments attended by slow suppuration, disposition for boils, styes, and similar eruptions, offensive secretion caused by catarrh, thick, yellow, lumpy discharges, offensive foot sweat, fetid perspiration of feet, hands, and axillae, scrofulous, rachitic children, large head and open fontanelles and sutures, distended abdomen, slow in walking; lymphatic, sanguineous temperament; small foreign bodies under the skin or in the larynx, suppurative inflammation of the connective tissue, constipation with ineffectual straining, and imperfect assimilation and consequent defective nutrition. The drugs in tablet form were alleged to be misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Further misbranding, Section 502 (a), the labeling of the articles in tablet form, namely, the mimeographed sheet, entitled "ABC Health Club" and the leaflets entitled "The most effective program," contained statements which were false and misleading since the articles were not effective for the purposes represented. The statements represented and suggested that the calcium fluoride, calcium phosphate, calcium sulfate, and iron phosphate were effective for disorders of the bones, teeth, connective tissue, and muscles; that the potassium chloride, potassium phosphate, potassium sulfate, and magnesium phosphate were effective for disorders of the brain, nerves, organic tissue, and liver; that the chloride of sodium-salt, sodium phosphate, sodium sulfate, and silica were effective for disorders of the blood, lymph, serums, and secretions; that the calcium phosphate and sodium phosphate were effective to reduce cellular activity and remedy calcium deficiency; and that the magnesium phosphate was effective to relieve pain or nervousness and to bring sleep. The articles were misbranded in these respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the articles in tablet form failed to bear adequate directions for use for the purposes for which they were intended, namely, the conditions for which they were offered in lectures delivered by L. W. Andrus at Chehalis, Wash., on September 4 and 18, 1952, and in a conversation with Food and Drug Inspector Rowland F. Walter, in September 1952, as follows:

Calcium fluoride—to increase rate of child's growth, to fluidify the blood, and for insomnia; calcium phosphate—to build new cells, for cancer and pneumonia, to slow the heart, and to enrich the blood; calcium sulfate—for affections of the bones, to reduce the rate of a child's growth, hemorrhage, liver weakness, and inactivity of the liver; iron phosphate—to enrich the blood; potassium chloride—to build nerve cells, for tuberculosis, to knock out fever. to fluidify the blood, to cure pneumonia, to thin the blood, to enrich the blood, and for insomnia; potassium phosphate—to fluidify the blood, for asthma, liver weakness, and inactivity of the liver; potassium sulfate—to enable one to grow up and mature emotionally, to cure pneumonia, for fever and to thin the blood, for liver weakness and inactivity of the liver, and for insomnia; magnesium phosphate—to build sensory nerves, for eyes, hearing, smell, and taste, to cure pneumonia, and for insomnia and nervousness; sodium chloride—for cancer, to fluidify the blood, to cure pneumonia, to thin the blood, to enrich the blood, and for insomnia; sodium phosphate—for liver weakness and inactivity of the liver; sodium sulfate—for insomnia; and silica—for tuberculosis.

Further misbranding, Section 502 (i) (3), the articles in tablet form were offered for sale under the names of other drugs, as follows: (calcium fluoride)—vitamin B; (calcium phosphate)—vitamin B complex; (calcium sulfate)—vitamin K; (iron phosphate)—vitamin C; (potassium chloride)—vitamin F; (potassium phosphate)—vitamin D; (potassium sulfate, sodium sulfate, and silica)—vitamins, the identities of which are not yet known; (magnesium phosphate)—vitamin E; (chloride of sodium-salt)—vitamin G or B_2; and (sodium phosphate)—vitamin A.

The articles in tablet form were alleged to be misbranded under Sections 502 (f) (1) and 502 (i) (3), as indicated above, while held for sale after shipment in interstate commerce.

Sodium phosphate and sodium sulfate—drugs in powder form (in bulk containers and as repacked). Misbranding, Section 502 (a), the labels of the

articles contained statements which represented and suggested that the sodium phosphate was an adequate and effective treatment for gas, heartburn, and other distress, and that the sodium sulfate would effect a direct liver reaction to remove stagnant bile, which statements were false and misleading since the sodium phosphate was not an adequate and effective treatment for the conditions stated and the sodium sulfate would not effect a direct liver reaction to remove stagnant bile; and, Section 502 (f) (2), the labels of the articles failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe methods or duration of administration, in such manner and form, as are necessary for the protection of users since their labeling did not bear warnings against use in case of nausea, vomiting, abdominal pain, or other symptom of appendicitis, nor against frequent or continued use which may cause dependency upon laxatives to move the bowels. The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

Calcium phosphate—drug in powder form (in bulk container and as repacked). Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purpose for which the article was intended. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

Drug in powder form repacked from unlabeled container into retail-sized containers and labeled "ABCO." Misbranding, Section 502 (a), the label statements "for revulsive hand, foot and abdominal hot applications. Neck, spine and congestive areas need ABCO sprinkled on a cold compress" were false and misleading since the article was not effective for the purposes stated and implied. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: June 17, 1953. L. W. Andrus, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the drugs be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare, and that the above-mentioned booklets, mimeographed sheets, and leaflets be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4085. Misbranding of pentobarbital sodium capsules and sulfathiazole tablets and conspiracy to violate the laws of the United States. U. S. v. Harry W. Wilson (Wilson Drug Co.), and Seth R. Medley. Pleas of guilty. Defendant Wilson fined $640 and sentenced to 6 months in jail; jail sentence suspended and defendant placed on probation for 1 year. Defendant Medley fined $114. (F. D. C. No. 33715. Sample Nos. 85336–K, 85345–K, 85346–K, 85350–K, 85351–K, 19318–L, 19319–L, 19332–L, 19340–L, 19348–L, 19356–L, 19364–L, 19367–L, 19368–L.)

INFORMATION FILED: December 16, 1952, Western District of Wisconsin, against Harry W. Wilson, trading as the Wilson Drug Co., Spooner, Wis., and Seth R. Medley, a physician.

ALLEGED VIOLATION: On or about November 6 and December 1 and 18, 1950, and January 5 and 24, March 4, 20, and 30, April 12, and May 2, 1951, while a number of *pentobarbital sodium capsules* and *sulfathiazole tablets* were

*See also Nos. 4083, 4084.

being held for sale after shipment in interstate commerce, Defendant Wilson repacked and dispensed to one, Thomas H. Kingsley, various quantities of such drugs without a prescription therefor, which acts resulted in the repackaged drugs being misbranded in violation of Section 301 (k).

The information charged further, in counts 2, 3, 6, 7, and 14, that as a part of the acts of repacking and dispensing the *pentobarbital sodium capsules* and *sulfathiazole tablets* on December 1 and 18, 1950, and as a part of the acts of repacking and dispensing the *sulfathiazole tablets* on May 2, 1951, Defendant Wilson filled out, on or about December 1, 1950, and May 2, 1951, paper forms the size and style of a physician's prescription form, commonly and usually containing directions to a pharmacist for the purpose of dispensing drugs; that after such forms had been filled out and as a part of the acts of repacking and dispensing, Defendant Medley, a physician, affixed his signature to such paper forms; that Thomas H. Kingsley, whose name appeared on the paper forms, was not a patient of Defendant Medley at any time; that after Defendant Medley had signed the paper forms, Defendant Wilson placed the paper forms in the prescription files of the Wilson Drug Co.; and that the act by Defendant Medley of signing the paper forms was an act which aided and abetted defendant Wilson in his violation of Section 301 (k).

The information alleged further, in count 15, that Defendants Wilson and Medley combined, conspired, and agreed together and with each other to violate Section 301 (k); that it was a part of the conspiracy that the defendants would dispense and cause to be dispensed, without labeling bearing adequate directions for use, *pentobarbital sodium capsules* and *sulfathiazole tablets* which had been shipped in interstate commerce into the State of Wisconsin and were being held for sale after such shipment; and that the acts of Defendant Wilson in repacking and dispensing the *pentobarbital sodium capsules* and the *sulfathiazole tablets* involved in counts 2, 3, 6, 7, and 14, and the act of Defendant Medley in aiding and abetting Defendant Wilson in the violation of Section 301 (k), as described above, were done in pursuance of the conspiracy and to effect the objects thereof.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the label of the repackaged *sulfathiazole tablets* failed to bear the common or usual name of the drug; and, Section 502 (f) (2), the labeling of the repackaged *sulfathiazole tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 5, 1953. The defendants having entered pleas of guilty, the court fined Defendant Wilson $640 and Defendant Medley $114. In addition, the court imposed a sentence of 6 months in jail against Defendant Wilson, but suspended the sentence, and placed this defendant on probation for 1 year.

4086. Misbranding of various drugs. U. S. v. Arthur Cox. Plea of not guilty. Tried to the court and jury. Verdict of guilty on 1 count and not guilty on remaining 11 counts. Sentence of 1 year in jail. Appeal taken and subsequently dismissed. (F. D. C. No. 31254. Sample Nos. 10869–L, 10915–L, 10916–L, 11283–L, 12055–L, 32108–L, 32453–L, 32454–L, 32456–L.)

INDICTMENT RETURNED: August 31, 1951, Southern District of Indiana, against Arthur Cox, Sullivan, Ind.

ALLEGED SHIPMENT: On or about March 4, 19, 26, 27, and 28, and April 1, 1951, from the State of Indiana into the States of Arkansas, Illinois, and Ohio, of various quantities of drugs, some of which were accompanied by labeling consisting of circulars entitled "Cooking Instructions For Herbs" and "United States Patent Office."

NATURE OF CHARGE: Drug consisting of a large amount of leaves resembling sunflower leaves, a small amount of eupatorium leaves and flowers, a trace of mint and dogwood leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (a), a statement on the label of the article represented and suggested that the article was a tonic, and a statement appearing in the labeling accompanying a portion of the article represented and suggested that such portion would be effective in the treatment of cancer. Such statements were false and misleading since the article was not a tonic and would not be effective in the treatment of cancer. Further misbranding, Section 502 (f) (1), the labeling of a portion of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a large amount of leaves resembling sunflower leaves and a small amount of unidentified leaf and stem fragments. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading since they represented and suggested that the article would be efficacious in the treatment of diabetes, whereas it would not be efficacious for that purpose.

Drug consisting of a large amount of dogwood leaves, fruit, and bark, a small amount of eupatorium leaves and flowers, mint leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading since they represented and suggested that the article would be efficacious in the treatment of diabetes, whereas it would not be efficacious for that purpose.

Drug consisting of a muddy, black aqueous liquid containing plant extractives. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of psoriasis, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant, and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a large amount of dogwood leaves, fruit, and bark, and small amounts of eupatorium leaves and flowers, leaves resembling sunflower leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (f) (1) the labeling of the article failed to bear adequate directions for use in the

treatment of cancer, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a cloudy, aqueous liquid containing plant extractives and having an offensive odor. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of vaginal trouble, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a large amount of leaves resembling sunflower leaves and small amounts of eupatorium leaves and flowers, dogwood leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of drawing of muscles, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a large amount of dogwood leaves, fruit, and bark, and small amounts of eupatorium leaves and flowers, mint leaves, leaves resembling sunflower leaves, and unidentified leaf and stem fragments. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of drawing of muscles, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of petrolatum and tobacco. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of rectal fistula, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Drug consisting of a muddy, aqueous extract, flavored with peppermint and containing nicotine. Misbranding, Section 502 (a), the word "Sinuses" displayed upon the label of the article was false and misleading. The word represented and suggested that the article would be effective in the treatment of diseases of the sinuses, whereas the article would not be effective for that purpose.

Drug for use in the treatment of cancer (ingredients unknown). Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease, symptom, and condition for which the article was prescribed, recommended, and suggested orally by the defendant; and the labeling of the article failed also to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was to be used.

Further misbranding, Section 502 (b) (1) and (2), each of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and none of the articles bore a label containing statements of the quantity of the contents.

DISPOSITION: The defendant filed a motion for dismissal of the indictment and for an order subjecting the grand jurors, the district attorney, and the stenographers to examination under oath, in open court, as to the grand jury proceedings. This motion was overruled on February 12, 1952. The defendant then entered a plea of not guilty, and on September 22, 1952, the case came on for trial before the court and jury. The trial was concluded on September 30, 1952, with the return by the jury of a verdict of guilty on the count relating to the drug which consisted of a muddy, black aqueous liquid containing plant extractives, and a verdict of not guilty on the remaining 11 counts relating to the other drugs. On January 12, 1953, the court sentenced the defendant to 1 year in jail. An appeal was taken by the defendant to the United States Court of Appeals for the Seventh Circuit and was dismissed on April 22, 1953, because of the defendant's failure to perfect his appeal.

4087. Misbranding of amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Thrifty Drug Stores Co., Inc., and Leonard Royce. Pleas of nolo contendere. Each defendant fined $500 and placed on probation for 3 years. (F. D. C. No. 34317. Sample Nos. 19161–L, 35013–L.)

INFORMATION FILED: December 30, 1952, District of Minnesota, against Thrifty Drug Stores Co., Inc., Rochester, Minn., and Leonard Royce, vice president and pharmacist for the corporation.

ALLEGED VIOLATION: On or about May 14 and June 19, 1951, while a number of *amphetamine sulfate tablets* and *Seconal Sodium capsules* were being held for sale at Thrifty Drug Stores Co., Inc., after shipment in interstate commerce, the defendants caused various quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged drugs failed to bear labels containing the common or usual name of the drugs; and, Section 502 (f) (2), the repackaged *amphetamine sulfate tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 1, 1953. Pleas of nolo contendere having been entered, the court fined each defendant $500 and placed each on probation for 3 years.

4088. Misbranding of Radiant Ozone Generator. U. S. v. 1 Device * * *. (F. D. C. No. 35233. Sample No. 42570–L.)

LIBEL FILED: May 21, 1953, Northern District of California.

ALLEGED SHIPMENT: In December 1948, by Mrs. Ann McClanahan and her husband, from Eldorado Springs, Mo.

PRODUCT: 1 *Radiant Ozone Generator* at Seaside, Calif. The device consisted essentially of a series of tubes, which were similar to neon tubes, with connections for attachment to a source of electric current.

LABEL, IN PART: "Radiant Ozone Generator Patent No. 2328640 2031 Main St., Kansas City, Mo."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of arthritis, angina, diphtheria, mumps, whooping cough, bladder and kidney trouble, blood disorders, anemia, cancer, diabetes, and catarrh, which were the conditions and purposes for which the device was intended to be used.

DISPOSITION: October 7, 1953. Default decree of condemnation and destruction.

4089. Misbranding of Radiant Ozone Generator. U. S. v. 1 Device * * *. (F. D. C. No. 35234. Sample No. 42568–L.)

LIBEL FILED: May 21, 1953, Northern District of California.

ALLEGED SHIPMENT: In December 1948, by Mr. and Mrs. Roma Hartline, from Eldorado Springs, Mo.

PRODUCT: 1 *Radiant Ozone Generator* at Seaside, Calif. The device consisted essentially of a series of tubes, which were similar to neon tubes, with connections for attachment to a source of electric current.

LABEL, IN PART: "Radiant Ozone Generator Patent No. 2328640 2031 Main St., Kansas City, Mo."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of inflammation of the kidneys, neuritis, neuralgia, blood clots, colds, diabetes, sinus trouble, headaches, nervousness, arthritis, sciatic rheumatism, asthma, heart trouble, kidney trouble, boils, poison oak, varicose veins, abnormal blood pressure, stomach cancer, stiff joints, breast cancer, appendicitis, chickenpox, colitis, toxic headaches, high blood pressure, enlarged heart, pleurisy, angina pectoris, asthma, pneumonia, sprains, throat trouble, bruise, cataracts, bloat, eczema, wens, broken bones, liver trouble, stomach trouble, gland trouble, bronchial trouble, rundown condition, cancerous growth, catarrh, constipation, watering eyes, pernicious anemia, paralysis, sore throat, piles, and ear ailment, which were the conditions and purposes for which the device was intended to be used.

DISPOSITION: October 7, 1953. Default decree of condemnation and destruction.

4090. Misbranding of Radiant Ozone Generator. U. S. v. 1 Device * * *. (F. D. C. No. 35235. Sample No. 42569–L.)

LIBEL FILED: May 21, 1953, Northern District of California.

ALLEGED SHIPMENT: In July 1952, by Mr. Roma Hartline, from Eldorado Springs, Mo.

PRODUCT: 1 *Radiant Ozone Generator* at Seaside, Calif. The device consisted essentially of a series of tubes, which were similar to neon tubes, with connections for attachment to a source of electric current.

LABEL, IN PART: "Radiant Ozone Generator Patent No. 2328640 2031 Main St., Kansas City, Mo."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of inflammation of the kidneys, neuritis, neuralgia, blood clots, colds, diabetes, sinus trouble, headaches, nervousness, arthritis, sciatic rheumatism, asthma, heart trouble, kidney trouble, boils, poison oak, varicose veins, abnormal blood pressure, stomach cancer, stiff joints, breast cancer, appendicitis, chickenpox, colitis, toxic headaches, high blood pressure, enlarged heart, pleurisy, angina pectoris, asthma, pneumonia, sprains, throat trouble, bruise, cataracts, bloat, eczema, wens, broken bones, liver trouble, stomach trouble, gland trouble, bronchial trouble, rundown condition, cancerous growth, catarrh, constipation, watering eyes, pernicious anemia, paralysis, sore throat, piles, and ear ailment, which were the conditions and purposes for which the device was intended to be used.

DISPOSITION: October 7, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4091. Adulteration and misbranding of tablets containing a mixture of mannitol hexanitrate and phenobarbital. U. S. v. Linn C. Williams (Banner Laboratories). Plea of guilty. Fine, $500. (F. D. C. No. 33789. Sample No. 17320–L.)

INFORMATION FILED: June 19, 1953, Southern District of California against Linn C. Williams, trading as the Banner Laboratories, South Pasadena, Calif.

ALLEGED VIOLATION: On or about September 5, 1951, the defendant caused to be given to a firm engaged in the business of shipping drugs in interstate commerce a guaranty to the effect that no drug delivered by the defendant under the guaranty would be adulterated or misbranded.

On or about January 25, 1952, the defendant caused to be delivered to the holder of the guaranty, at Los Angeles, Calif., a number of *tablets containing a mixture of mannitol hexanitrate and phenobarbital* which were adulterated and misbranded.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the tablets differed from that which they were represented to possess since each tablet was represented to contain ½ grain of mannitol hexanitrate and each tablet contained less than that amount of mannitol hexanitrate.

Misbranding, Section 502 (a), the label statement "Each tablet contains mannitol hexanitrate ½ grain" was false and misleading.

DISPOSITION: July 6, 1953. The defendant having entered a plea of guilty, the court fined him $500.

4092. Adulteration and misbranding of estrogenic substances. U. S. v. 15 Cartoned Vials * * *. (F. D. C. No. 34895. Sample No. 58945–L.)

LIBEL FILED: March 17, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: On or about January 12, 1953, from Jersey City, N. J.

PRODUCT: 15 cartoned 20 cc. vials of *estrogenic substances* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (c), the actual strength of the article, namely, an amount of natural estrogens from pregnant mares' urine

equivalent to 12,600 International Units of estrone per cubic centimeter of solution, differed from the strength which the article was represented to possess, namely, an amount of natural estrogens from pregnant mares' urine equivalent to 20,000 International Units of estrone per cubic centimeter of solution.

Misbranding, Section 502 (a), the label statement "Natural Estrogens from pregnant mares' urine equivalent to 20,000 international units of estrone per cubic centimeter" was false and misleading as applied to the article, which contained per cubic centimeter of solution an amount of natural estrogens from pregnant mares' urine equivalent to 12,600 International Units of estrone.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: April 22, 1953. Default decree of condemnation and destruction.

4093. Adulteration and misbranding of estrogenic substances. U. S. v. 20 Cartoned Vials * * *. (F. D. C. No. 34896. Sample No. 62341-L.)

LIBEL FILED: March 17, 1953, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about January 12, 1953, from Jersey City, N. J.

PRODUCT: 20 cartoned 20 cc. vials of *estrogenic substances* at St. Louis, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (c), the actual strength of the article, namely, an amount of natural estrogens from pregnant mares' urine equivalent to 13,400 International Units of estrone in each cubic centimeter of solution, differed from the strength which the article was represented to possess, namely, an amount of natural estrogens from pregnant mares' urine equivalent to 20,000 International Units of estrone in each cubic centimeter.

Misbranding, Section 502 (a), the label statement "Natural Estrogens from pregnant mares' urine equivalent to 20,000 international units of estrone per cubic centimeter" was false and misleading as applied to a product which contained per cubic centimeter of solution an amount of natural estrogens from pregnant mares' urine equivalent to less than 20,000 International Units of estrone, namely, not more than 13,400 International Units of estrone per cubic centimeter.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: April 10, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4094. Misbranding of cigarettes. U. S. v. 46 Cartons, etc. Answer filed by claimant denying that product was a drug. Decision for the Government. Decree of condemnation. (F. D. C. No. 33295. Sample No. 38038-L.)

LIBEL FILED: June 13, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about February 29, 1952, by G. A. Georgopulo & Co., from New York, N. Y.

PRODUCT: 46 cartons, each containing 10 packages, of *cigarettes* at Jersey City, N. J., together with a number of leaflets entitled "How Fairfax Cigarettes may help you." The article was represented, in the leaflet, to contain tobacco, triethylene glycol, and chlorophyll.

*See also Nos. 4084, 4086, 4091-4093.

LABEL, IN PART: (Package) "Fairfax Cigarettes * * * Sterling Tobacco Corp., New York, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a) certain statements in the above-mentioned leaflet accompanying the article were false and misleading. The statements represented and suggested that the article would be effective in preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, meningitis, tuberculosis, mumps, otitis media (middle ear infection), and meningopneumonitis psittacosis (parrot fever), and that it would be innocuous for persons suffering from circulatory diseases, high blood pressure, and various heart conditions. The article would not be effective in preventing the conditions stated and implied, and it was not innocuous for persons in the categories mentioned.

DISPOSITION: On September 3, 1952, the Sterling Tobacco Corp. appeared as claimant and filed an answer denying that the product was a drug and that it was misbranded. Interrogatories were served upon the claimant by the Government. The interrogatories were answered in part by the claimant, after which, pursuant to an agreement between the parties, the case was submitted to the court for determination of the issue of whether or not the product was a drug.

On June 10, 1953, the court handed down the following opinion:

MEANEY, *District Judge:* "This matter is submitted on the following agreed set of facts:

"The claimant introduced into interstate commerce 46 cartons of 'Fairfax cigarettes' with 51 accompanying leaflets entitled 'How Fairfax Cigarettes may help you,' all of which the libellant caused to be seized under the provisions of 21 U. S. C. 301 et seq. (1946 Ed.). The libel, as amended, alleges that the cigarettes are a drug and were misbranded when introduced into and while in interstate commerce.

"It is agreed by the parties hereto that the only question to be decided is whether the seized article is a drug within the meaning of the Federal Food, Drug and Cosmetic Act, above cited. It is further agreed that if the seized article be found not to be a drug, the libel should be dismissed for lack of jurisdiction of the subject matter. If, however, it be found to be a drug, misbranding is conceded and a decree of condemnation will be entered.

"The term 'drug' in this connotation is defined in the Federal Food, Drug and Cosmetic Act as follows:

> (g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts or accessories. (21 U. S. C. A. 321.)

"Because of the wording of this provision, with particular reference to (g) (2), it is important to examine the representations of the circular accompanying the article in question. The libellant contends that the leaflet accompanying the article suggests and represents that the article is effective in preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps, otitis media (middle ear infection), meningopneumonitis psittacosis (parrot fever). Libellant further contends that claimant represents that the smoking of these cigarettes is innocuous for persons suffering from circulatory diseases, high blood pressure and various heart conditions. There is no doubt that the leaflets accompanying the cigarettes fall within

the meaning of labeling in the instant case. *Kordel v. United States*, 335 U. S. 345. If there be an indication of intent to use the article for the cure or mitigation, or treatment or prevention of disease in man, then clearly the subject matter of the libel is to be considered a drug within the meaning of the Act. As is said in Senate Report No. 361, 74th Congress, 1st Session, 'The manufacturer of the article through his representations in connection with its sale, can determine the use to which the article is to be put.'

"Against this analysis of the leaflets the claimant contends that its only substantial assertion concerning the cigarettes is that they increase one's smoking pleasure. If this be so, then the extensive references to 'miracle vapor' and its seeming effects in the reduction of the frequency of respiratory diseases, and the somewhat more than casual references to the diseases aforementioned, would appear to have no other purpose than to mislead the unwary. In those fields where there is heavy competition, hucksters, as the over impulsive advertising copy writers seem to be slightingly denominated in the trade, vie with each other in the composition of extravagant descriptions of the beneficial qualities of their product, or in insinuations or indirectness from which the untutored mind would infer extraordinary ameliorative results. Exactness, completely truthful statements and objective verisimilitude are frequently subordinated to blatant, spectacular, suggestive or dubious representations in order to break down sales resistance or to create a demand for a product hitherto not found necessary to the happiness or the well-being of the general public.

"This is certainly not the first occasion on which cigarette advertisers and representatives of the public have clashed. See *Federal Trade Commission* v. *Liggett & Myers Tobacco Company*, 108 F. Supp. 573, 577 (S. D. N. Y. 1952). Perhaps in a field where, generally speaking, competition is met by advertising and labeling rather than by price or even perhaps by substantial differences in quality, such conflicts are almost inevitable as manufacturers tread near the statutory boundary. Certainly, Congress in drawing this boundary had in mind that the public should be adequately and truthfully informed as to what it is purchasing. The Federal Food, Drug and Cosmetic Act must be construed so as to effectuate the purpose of protecting the buying public, which is largely beyond self-protection in the circumstances of modern life. *62 Cases of Jam* v. *United States*, 340 U. S. 593, 596 (1951); *Kordel* v. *United States*, *supra*: *United States* v. *Dotterweich*, 320 U. S. 277, 280 (1943).

"The question, therefore, is whether the public, having in mind the specious statements of the leaflets, would buy Fairfax cigarettes primarily for smoking enjoyment or with the hope of mitigating, curing or preventing disease.

"In *Bradley* v. *United States*, 264 Fed. 79 (C. C. A. 5, 1920), mineral water was sold in interstate commerce with the labeling, 'Recommended in the treatment of Bright's disease' and other named diseases. The court was called upon to decide whether these words, properly construed, meant that the water had curative or therapeutic qualities. Claimant argued that the label made no statement regarding these qualities. The court held, however, that the use of the above-quoted words in the label 'could only mean that the use of the water in the treatment of the diseases named would effect a cure or alleviation of such diseases; otherwise, why recommend it?' (p. 81).

"'* * * The contention is made that the water condemned in this case is not a drug, within the meaning as used in the act. * * * As Justice Hughes says, in *Seven Cases* v. *U. S.* 239, U. S. 517 * * * "That false and fraudulent representations may be made with respect to the curative effect of substances is obvious," and when so made of water it seems to us that it would be trifling to say that water ordinarily is not a drug in the true meaning of the word, and therefore does not fall within the condemnation of * * * the act. If the allegations of the libel are true, the claimant has put the substance, water, in interstate commerce with the recommendation that it possesses certain elements or ingredients which are curative, or at least alleviative, for the diseases named in the label. He will not be heard now to say the substance recommended is water, and not a drug. Such a construction would nullify the act of Congress.' (pp. 81, 82).

"Although the case at bar may be less obvious, the principles involved are nevertheless the same as those of the *Bradley* case. If claimant's labeling was such that it created in the mind of the public the idea that these cigarettes could be used for the mitigation or prevention of the various named diseases,

claimant cannot now be heard to say that it is selling only cigarettes and not drugs.

"On this point legislative intent is clear. 'The use to which a product is to be put will determine the category into which it will fall. If it is to be used only as a food it will come within the definition of food and no other. If it contains nutritive ingredients but is sold for drug use only, as clearly shown by the labeling and advertising, it will come within the definition of drug, but not that of food. If it is sold to be used both as a food and for the prevention or treatment of disease it would satisfy both definitions and be subject to the substantive requirements for both. The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product.' (Senate Report No. 361, 74th Congress, 1st Session from the Committee on Commerce Report to accompany S. 5).

"How, then, has the manufacturer in the case at bar represented his product to the public? What is the nature and import of the labeling as shown by the leaflet?

"Claimant, understandably, does not believe it is selling drugs. It admits that the product has none of the curative or preventive powers implied in the leaflet. But throughout the leaflet claimant has tried to capture a share of the cigarette market by a subtle appeal to a natural and powerful desire on the part of us all to avoid the infectious diseases or ailments therein mentioned. Should the buying public or some portion of it turn to Fairfax cigarettes, it would most likely do so because of the means claimant has used to bring the cigarettes to public attention. It is not likely that the buying public would ordinarily carefully study or weigh each word in the leaflet. 'The ultimate impression upon the mind of the reader arises from the sum total of not only what it said but also of all that is reasonably implied.' *Aronberg* v. *Federal Trade Commission*, 132 F. 2d 165, 167 (C. C. A. 7, 1942). The clear import of the leaflet is at least that the smoking of the cigarettes will make it less likely that the smoker will contract colds or other virus infections. This is enough to bring the product within the statutory meaning of 'drug.' If claimant wishes to reap the reward of such claims, let it bear the responsibility as Congress has seen fit to impose it. *United States* v. *Dotterweich*, *supra:* cf. *Barnes* v. *United States*, 142 F. 2d 648 (D. C. A. 9, 1944)."

Pursuant to the above opinion, the court, on June 29, 1953, entered a decree of condemnation and ordered that the product be destroyed. On September 9, 1953, with the consent of the parties, an amended decree was entered providing for the release of the product under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4095. Misbranding of Yo-Zyme yogurt tablets. U. S. v. 63 Bottles, etc. (F. D. C. No. 33313. Sample Nos. 1162–L, 1163–L.)

LIBEL FILED: July 7, 1952, Southern District of Florida.

ALLEGED SHIPMENT: On or about March 17, 1952, by MacDonald Laboratories, Inc., from St. Paul, Minn.

PRODUCT: 63 150-tablet bottles and 86 500-tablet bottles of *Yo-Zyme yogurt tablets* at Orlando, Fla., together with a number of mailing cards entitled "Yo-Zyme" and a number of leaflets entitled "The Story of Yo-Zyme" and "Yo-Zyme For Health and Vitality."

Examination showed that the product contained a small number of viable streptococci and lactobacilli organisms.

LABEL, IN PART: (Bottle) "Yo-Zyme Yogurt Cpd. Tablets" or "Yo-Zyme Yogurt Cpd. Healthfood Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the bottle labels and the above-mentioned

mailing cards and leaflets accompanying the article, were false and misleading. The statements represented and suggested that the article was effective to increase vitality, to prevent "flu," colds, and other infections, to lessen fatigue, to increase resistance to disease, to relieve nervousness, to improve complexion, to build blood, and to implant and maintain a lactic acid bacterial culture in the intestines. The article was not effective for such purposes.

DISPOSITION: MacDonald Laboratories, Inc., claimant, having filed a motion for the removal of the case to the District of North Dakota, the court entered an order, on November 24, 1952, directing such removal. Thereafter, since the claimant failed to make any further appearance in the case and since it appeared that default judgment could not be entered in the District of North Dakota, an order was entered by the United States District Court for the District of North Dakota, transferring the case back to the Southern District of Florida. Following such transfer, the United States District Court for the Southern District of Florida entered a default decree of condemnation and destruction on September 4, 1953.

4096. Misbranding of Matte (maté). U. S. v. 53 Cylinders * * *. (F. D. C. No. 34162. Sample No. 44418–L.)

LIBEL FILED: November 20, 1952, District of Massachusetts.

ALLEGED SHIPMENT: On or about July 22, 1952, by David Komisar & Son, Inc., from New York, N. Y.

PRODUCT: 53 cylinders of *Matte* (maté) at Boston, Mass. Examination showed that the product was maté.

LABEL, IN PART: (Cylinder) "Gold Brande Matte The Energizing Brazilian Tea Nature's Golden Drink delicious stimulating * * * Net Weight ½ Pound."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements, namely, "The Energizing Brazilian Tea * * * is prepared identically as is common tea * * * energizing * * * supplies vitamins and minerals * * * tonic effects * * * its natural dietetic properties aid the body to throw off excess uric acid * * * supplies quick energy and helps to resist unusual mental and physical strain," were false and misleading since the article was not tea, did not provide nutritionally significant amounts of vitamins and minerals, and was not effective in the treatment of the conditions stated and implied.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: David Komisar & Son, Inc., appeared as claimant and filed an answer denying that the product was misbranded. Thereafter, upon agreement of the parties, the case was removed for trial to the United States District Court for the Eastern District of New York. Interrogatories subsequently were filed by the Government on April 15, 1953. Upon failure of the claimant to answer the interrogatories, a motion was filed by the Government to strike the claimant's answer to the libel and for a default decree of condemnation. No opposition to such motion having been interposed, the court, on September 4, 1953, granted the motion and entered a default decree of condemnation and destruction.

4097. Misbranding of Azalias Medicine. U. S. v. 100 Bottles * * *. (F. D. C. No. 34668. Sample No. 19903–L.)

LIBEL FILED: February 18, 1953, District of Minnesota.

ALLEGED SHIPMENT: On or about November 3, 1952, by Dr. A. Smith, from Omaha, Nebr.

PRODUCT: 100 4-ounce bottles of *Azalias Medicine* at Underwood, Minn.

LABEL, IN PART: (Bottle) "Azalias Medicine Contents: Ammonium Chloride Ammonium Carbonate Guiacol Carbonate Guiacol Syrup of Prunus Virginiana Compound mixture of Syrup of Glycyrrhiza * * * Azalias Medicine For Colds, Coughs, Influenza, Pneumonia, Tuberculosis and all throat and lung inflammation."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for colds, coughs, influenza, pneumonia, tuberculosis, and all throat and lung infections, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: April 27, 1953. Default decree of condemnation. The court ordered that the product be turned over to the Food and Drug Administration.

4098. Misbranding of Kloro solution. U. S. v. 41 Bottles * * *. (F. D. C. No. 31765. Sample No. 37743–L.)

LIBEL FILED: October 9, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about August 30, 1951, by Preston Laboratories, Inc., from Chicago, Ill.

PRODUCT: 41 8-ounce bottles of *Kloro solution* at Maspeth, N. Y.

LABEL, IN PART: (Bottle) "Miracle Kloro Solution * * * Ideally suited for * * * healing gums * * * Marked relief in Sinusitis and Chronic Nasal Conditions have resulted from continuous irrigation with Chlorophyll alkaline solution * * * healing * * * when applied to cuts, burns, ulcers and wounds * * * Contains: Special prepared Chlorophyllins, Pot. Bicarb., Borax, Thymol, Menthol, Glycerin, Sodium Ben., Sod. Chloride, Aromatic Oils Water."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label of the article were false and misleading since the statements represented and suggested that the article was effective in the treatment of diseases of the gums, sinuses, chronic nasal diseases, cuts, burns, ulcers, and wounds, whereas the article was not effective in the treatment of such conditions.

DISPOSITION: January 16, 1952. Default decree of condemnation and destruction.

4099. Misbranding of Desert Springs Home Restorative Baths. U. S. v. 103 9/12 Cases, etc. (F. D. C. No. 34085. Sample No. 40670–L.)

LIBEL FILED: November 14, 1952, Western District of Washington.

ALLEGED SHIPMENT: On or about August 14 and 15, 1952, by the Kal Central Distributing Co., from Pasadena, Calif.

PRODUCT: 103 9/12 cases, each full case containing 12 cartons and each carton containing 1 dozen packets, of *Desert Springs Home Restorative Baths* at Seattle, Wash., together with 100 sheets and 40 placards entitled "See for Yourself," 1,000 pamphlets entitled "Desert Springs Home Restorative Baths," 1 mimeographed letter entitled "Your Own Private Mineral Spring," 1 three-page mimeographed article entitled "No. 6. Direct Sales Approach," 4 mimeo-

graphed sheets entitled "No. 1. Here Is An Important New Product," 4 mimeographed sheets entitled "No. 2. Here Is A New Discovery." 4 mimeographed sheets entitled "No. 3. Now . . . At Last!" 4 mimeographed sheets entitled "No. 4. One of the Loveliest." 3 mimeographed sheets entitled "No. 5. Thousands and Thousands," 1 mimeographed sheet entitled "No. 7. Immediate Release." 1 mimeographed sheet entitled "No. 8. Immediate Release," 4 letters dated August 14 and 19 and September 10 and 18, 1952, 1 copy of a newspaper mat entitled "New Desert Springs Home Restorative Mineral Baths," and 2 business reply cards entitled "Dear Editor."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the above-described cartons, sheets, pamphlets, letters, mimeographed sheets, newspaper mat, placards, and business reply cards accompanying the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis, rheumatism, neuritis, overwork, tired, aching back, stiff joints, nervous strain, aftermath of old injuries, tensions that prevent sound sleep, a worn-out condition, sleeplessness, all kinds of ailments, and for providing in one's home restorative benefits and curative effects equal to those derived by visiting world-famous mineral spring health resorts. The article was not an adequate and effective treatment for such conditions or purposes.

DISPOSITION: May 18, 1953. Default decree of condemnation and destruction.

4100. Misbranding of phonograph records. U. S. v. 23 Records, etc. Tried to the court. Judgment for the claimant. Judgment reversed upon appeal. Decree of condemnation and destruction. (F. D. C. No. 20564. Sample No. 8839–H.)

LIBEL FILED: July 25, 1946, Eastern District of New York.

ALLEGED SHIPMENT: On or about May 31, 1946, by DeLuxe Record Co., Inc., from Linden, N. J.

PRODUCT: 23 *phonograph records* at Brooklyn, N. Y., together with a number of accompanying display cards entitled "DeLuxe Records Presents Time to Sleep A Tested Method of Inducing Sleep Conceived and Transcribed by Ralph Slater" and a number of accompanying posters headed "A 'Dream Girl' Shows a New Way to Dreamland."

Each record was contained in an album which bore a picture of the head and shoulders of a young woman in deep slumber and which contained a leaflet reading, in part, "Sleep with this amazing record 'Time to Sleep'" and a certificate entitled "Sleep Guaranteed."

LABEL, IN PART: (Record) "Time to Sleep A Tested method to induce sleep Prepared and transcribed by Ralph Slater."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and designs in the labeling of the article were false and misleading. The statements and designs represented and suggested that the article when used as directed would induce sleep, whereas the article was not capable of affecting that function of the body.

DISPOSITION: Ralph Slater, claimant, filed an answer denying (1) that the records were a device within the meaning of the law and (2) that the records were misbranded. The case came on for trial before the court without a jury on January 4, 1950, and, at its conclusion, the case was taken under advisement by the court. On March 9, 1950, the following opinion was handed down:

RAYFIEL, *District Judge:* "Under the libel of information filed herein the government seeks the seizure and condemnation of certain phonograph records, together with the albums in which they were contained, as well as a quantity of leaflets, guarantees and display cards, all in said libel identified and described, on the ground (1) that the said records are devices, and, with their accompanying graphic and printed matter, are misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, and, (2) that the same were shipped in interstate commerce in violation of the said Act, and are therefore illegally within the jurisdiction of this Court.

"Ralph Slater, the claimant herein, answering the said libel, denies that the aforementioned records are devices within the meaning of the said Act, and, further, denies that the said records, albums and their accompanying leaflets, guarantees and display cards were misbranded, as alleged in the libel.

"A pre-trial conference was held and the resultant order, dated May 7th, 1948, provided that one of each of the items involved, to wit: a record, album, guarantee, leaflet, poster and display card, be received in evidence as exhibits without objection, and that it be stipulated and conceded by the defendant that duplicates thereof were shipped in interstate commerce from a point in New Jersey to a point in Brooklyn, within the Eastern District of New York.

"The defendant has not disputed the fact that the printed and graphic matter appearing on the record, album, guarantee, poster and display card constitute 'labeling' within the meaning of subdivision 'm' of section 321 [201] of the Act. Hence, two questions remain to be answered.

(1) Is the phonograph record hereinabove referred to a device, as defined by subdivision 'h' of section 321 [201] of the Act?

(2) Is the said record misbranded, in violation of subdivision 'a' of section 352 [502] of the Act, in that the labeling is false or misleading in any manner?

"As to the first question: *Is the record a device?*—For the purpose of the Food, Drug and Cosmetic Act the word 'device' (with certain exceptions not here pertinent) is defined as an instrument, apparatus or contrivance including its components, parts or accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, or (2) to affect the structure or any function of the body of man or other animals.

"Funk and Wagnalls New Standard Dictionary definies 'apparatus' as 'any complex device or machine designed or prepared for the accomplishment of a special purpose; also a collection of tools, appliances, materials, etc.' . . . . The same authority defines 'contrivance' as '. . . a project or artifice; an apparatus or invention . . . . especially . . . . for scientific or professional purposes . . . .' Clearly the record comes within none of those definitions, nor does it, or its accompanying printed matter purport that it may be effectively used (1) for the *diagnosis, cure, mitigation, treatment or prevention of disease* or (2) *to affect the structure of or any function of the body.* In my opinion the word 'function' in subdivision 'h' of section 321 [201] of the Act is limited in meaning to the specific power of action and operation of an organ of the body, such as the brain, heart or liver. Funk and Wagnalls gives as a definition of 'function' the following: 'Physiol. A special office in the animal economy that has as its agent or instrument a specific organ or system of organs; the normal action of any organ or set of organs.'

"It is this Court's opinion that the 'devices' contemplated by the statute is such a machine or apparatus which is applied to or injected into the body or some organ thereof or whose current or rays enter the body.

"As to the second question: *Is the record misbranded in that the labeling is false and misleading?*—I find nothing in the record, or in the printed matter hereinabove referred to, which constitutes misbranding within the meaning of the statute herein involved. It appears that there is more than a modicum of self-opinion in the claimant's references to his own talents and experience, but those probably extravagant statements do not extend to the record, except possibly in some detail which I do not think was a persuasive factor in the sale of the record.

"Bernard Locke, a clinical psychologist associated with the Veterans Administration, and Dr. Wilbur, a psychiatrist, testifying in behalf of the government, stated that they had tested the record on a number of patients and

had found it to be ineffective. Those tests, however, were made under most unfavorable conditions. All of the subjects were psychoneurotic war veterans who suffered from insomnia as one of a number of prevailing symptoms. They could hardly be expected to co-operate and respond to suggestion as the record indicates is a necessary prerequisite. Mr. Locke testified that he performed the test because he was interested in seeing whether it (the record) would *cure even* psychoneurotic cases. Slater made no such claim.

"Dr. Hoffman, a well-known psychiatrist, testified in behalf of the claimant. He stated that treatment of the type indicated by the record had been employed by the medical profession; further, that while the record would have little beneficial effect in cases of persons suffering from organic diseases or defects, it could be successfully used in other cases. Music and suggestion are frequently used to mitigate and relieve insomnious conditions.

"Accordingly, I find for the claimant, who is entitled to the return of the articles seized by the government.

"Submit decree in conformity herewith."

In accordance with the above opinion, the court, on April 13, 1950, entered judgment in favor of the claimant and ordered that the records and accompanying literature be returned to the claimant.

An appeal was taken by the Government to the United States Court of Appeals for the Second Circuit, and on November 7, 1951, the following opinion was handed down:

WOODBURY, *Circuit Judge:* "The United States of America filed a libel of information in the court below under Sec. 304 (a) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1044; 21 U. S. C. Sec. 334 (a)) seeking the seizure and condemnation of certain phonograph records, and various accompanying items of printed and graphic matter, all of which were moving or had moved in interstate commerce. The phonograph records are entitled in part 'Time To Sleep,' and their accompanying literature consists of (1) an album in part entitled, 'De Luxe Records Presents Time to Sleep A Tested Method of Inducing Sleep Conceived and Transcribed by Ralph Slater,' (2) a leaflet in part reading: 'Sleep With This Amazing Record "Time To Sleep,"' (3) a certificate entitled 'Sleep Guaranteed,' (4) display cards entitled 'De Luxe Records Presents Time To Sleep,' and (5) a poster headed 'A "Dream Girl" Shows a New Way to Dreamland.' The court below after full hearing without a jury filed a memorandum opinion in accordance with which it entered a final decree ordering the libel dismissed and the libeled property returned to Ralph Slater, the claimant. The United States thereupon took this appeal.

"Two questions are presented. The first is whether a phonograph record is a 'device' within the meaning of Sec. 201 (h) of the Act. 21 U. S. C. Sec. 321 (h). The second question, which arises only if the first is answered in the affirmative, is whether the records in question are misbranded within the meaning of Sec. 502 (a) id. 21 U. S. C. Sec. 352 (a).

"Section 201 (h) of the Act under consideration provides in material part that 'The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.'

"Certainly a phonograph record, if not itself an instrument or an apparatus, is a contrivance. And moreover, it is without a question a component, part or accessory of a phonograph, or like record playing machine, which in its turn is without any doubt at all an instrument, apparatus or contrivance. The real question therefore is whether the libeled records were intended for either of the uses described in (1) or (2) of Sec. 201 (h), supra. Obviously the records were intended for use in the cure, mitigation, treatment or perhaps prevention of insomnia. But the medical experts who testified at the trial were agreed that insomnia is not a disease, but is a symptom of a disease, usually although not necessarily a neurological one, or of an emotional disturbance of some kind. Thus it may be argued that the records do not fall within the coverage of (1) above.

"However, all the expert witnesses who testified on the point were unanimous that sleep is a function of the body, or body and mind, of man and other animals, and this testimony brings the records within the terms of (2), supra, for their intended use was to affect that function, i. e., to induce sleep in those who needed it but had difficulty in obtaining enough. Without further laboring the point it will suffice to say that the records involved are 'devices' within the meaning of Sec. 201 (h) (2) of the Act.

"The question therefore arises whether the records are misbranded within the meaning of Sec. 502 (a) of the Act in that their labeling (which term includes not only the actual labels on the records and their containers or wrappers, but also any other written, printed, or graphic matter accompanying them (Sec. 201 (m) id.), 'is false or misleading in any particular.'

"The sounds produced by the record when played upon any standard phonograph or record player are the voice of Ralph Slater, the claimant, superimposed upon faint background music. On the side of the record intended to be played first the claimant explains how the record is to be used, in the course of which he says: 'You may not be able to teach yourself to sleep, yet listening to me and believing as you must believe, that I can help you, makes insomnia a thing of the past.'

"The statements on the album stress Slater's 'uncanny' and 'phenomenal' power to induce sleep by suggestion, even though not personally present, his long and arduous training, and the fact that his method is well tested and efficacious 'in the treatment of unusual, difficult psychoneurotic cases.' In the leaflet it is stated, among other things, that 'Mr. Slater, who has put people to sleep on the stage, and by various powers of remote contact, has translated his power into this record which will be invaluable to everyone who suffers from insomnia.' The certificate guarantees that the record 'will induce blissful sleep in the most delightful manner,' and the display card and poster, although they seem innocuous enough considered separately and apart from their context, convey the same impression.

"Reading the foregoing labeling together, in the way it would be read by persons who might be sufficiently interested to read it at all, conveys the impression that the record is a cure-all for insomnia from whatever cause, or at least is an adequate substitute for medication.[1] This is not only misleading but also false, for the evidence clearly establishes that the record can not possibly do as much. Indeed the expert witnesses called by the Government who had made actual tests of the record on persons suffering from insomnia, testified unanimously that it proved wholly ineffectual, and one of them went even further and said that it might in some cases be actually harmful in that a person might resort to it for trial and in so doing postpone medical care and treatment for the cause of the insomnia from which he suffered. And the medical experts called by the claimant did not flatly contradict the Government's evidence. Although they said that in their opinion based upon hearing the record a few times (they had not conducted actual tests) it might prove helpful in certain cases of insomnia, they freely admitted on cross-examination that some of the statements in the labeling were 'extravagant.' For instance they would by no means go so far as to say, indeed they denied, that the record 'makes insomnia a thing of the past,' or that it would be 'invaluable to everyone who suffers from insomnia.' Thus it cannot be said that the labeling of the record is not 'false or misleading in any particular' and from this it follows that the record is misbranded within the meaning of Sec. 502 (a) of the Act.

"The decree of the District Court is vacated and set aside and the case is remanded to that Court for further proceedings consistent with this opinion."

On December 15, 1953, following the remanding of the case to the United States District Court, an order was entered vacating the judgment of April 13, 1950, and providing for the condemnation and destruction of the records and accompanying literature under seizure.

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[1] Indeed on the inside of the front cover of the album the statement is made in a testimonial that Slater's "aim is to discourage the fad for sleeping pills."

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4086) Prosecution contested.
[2] (4094) Seizure contested. Contains opinion of the court.
[3] (4100) Seizure contested. Contains opinions of the courts.

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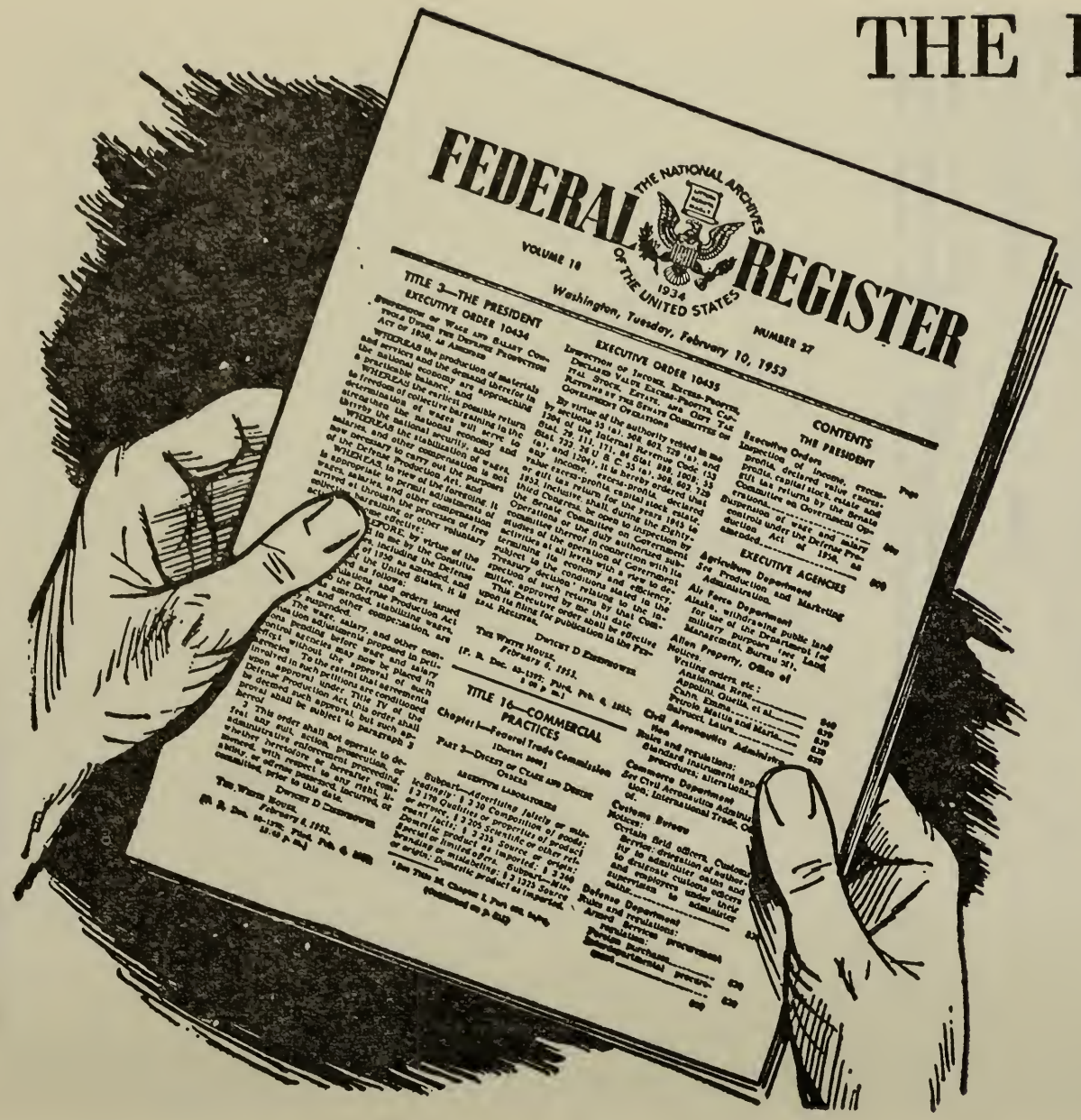

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4101–4120

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *April 27, 1954.*

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*For presence of a habit-forming narcotic without warning statement, see No. 4111; omission of, or unsatisfactory, ingredients statements, No. 4110; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4110, 4111; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4110, 4116.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4101. Misbranding of Dexedrine Sulfate tablets. U. S. v. Constable Drug Co. Plea of nolo contendere. Fine, $100. (F. D. C. No. 34329. Sample No. 35399–L.)

INFORMATION FILED: July 15, 1953, Northern District of Iowa, against the Constable Drug Co., a partnership, Storm Lake, Iowa.

NATURE OF CHARGE: On or about May 13, 1952, while a quantity of *Dexedrine Sulfate tablets* were being held for sale at the Constable Drug Co., after shipment in interstate commerce, the defendant caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer the drug. This act of dispensing was contrary to Section 503 (b) (1), and resulted in the drug so dispensed being misbranded while held for sale.

DISPOSITION: July 15, 1953. The defendant having entered a plea of nolo contendere, the court fined it $100.

4102. Misbranding of Dexedrine Sulfate tablets and Seconal Sodium capsules. U. S. v. Harold Saber (Nace Drug Co.). Plea of guilty. Fine of $150 on count 1; imposition of sentence on count 2 suspended and defendant placed on probation for 18 months. (F. D. C. No. 34355. Sample Nos. 37331–L, 37897–L.)

INFORMATION FILED: March 13, 1953, District of New Jersey, against Harold Saber, trading as the Nace Drug Co., Asbury Park, N. J.

NATURE OF CHARGE: On or about May 16 and 20, 1952, while quantities of *Dexedrine Sulfate tablets* and *Seconal Sodium capsules* were being held for sale at the Nace Drug Co., after shipment in interstate commerce, the defendant caused quantities of the drugs to be dispensed upon requests for refills of written prescriptions, without obtaining authorization by the prescribing physician. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the drugs so dispensed being misbranded while held for sale.

DISPOSITION: June 12, 1953. The defendant having entered a plea of guilty, the court fined him $150 on count 1, suspended the imposition of a sentence on count 2, and placed him on probation for 18 months.

4103. Misbranding of sulfathiazole tablets, secobarbital sodium capsules, dextro-amphetamine sulfate tablets, and thyroid tablets. U. S. v. Rio Grande Pharmacy, Inc. Plea of guilty. Fine, $300. (F. D. C. No. 34324. Sample Nos. 21374–L, 21377–L to 21379–L, incl., 22510–L, 22515–L.)

INFORMATION FILED: May 1, 1953, Southern District of Texas, against Rio Grande Pharmacy, Inc., Harlingen, Tex.

NATURE OF CHARGE: On or about June 9, 10, 12, and 13, 1952, while a number of *sulfathiazole tablets*, *secobarbital sodium capsules*, *dextro-amphetamine sulfate tablets*, and *thyroid tablets* were being held for sale at the Rio Grande Pharmacy, Inc., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without prescriptions from practitioners licensed by law to administer the drugs. These acts of dispensing were contrary to Section 503 (b) (1), and resulted in the drugs so dispensed being misbranded while held for sale.

DISPOSITION: May 12, 1953. The defendant having entered a plea of guilty, the court fined it $300.

4104. Misbranding of amphetamine sulfate tablets, dextro-amphetamine sulfate tablets, and sulfathiazole tablets. U. S. v. Albert D. Phillips (Moon Store). Plea of nolo contendere. Fine, $200. Imposition of jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 34850. Sample Nos. 22252–L, 22253–L, 46588–L, 46590–L.)

INFORMATION FILED: June 2, 1953, Eastern District of Louisiana, against Albert D. Phillips, trading as the Moon Store, New Orleans, La.

NATURE OF CHARGE: On or about September 17, 23, and 24, 1952, while a number of *amphetamine sulfate tablets*, *dextro-amphetamine sulfate tablets*, and *sulfathiazole tablets* were being held for sale at the Moon Store, after shipment in interstate commerce, the defendant caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer the drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: July 15, 1953. The defendant having entered a plea of nolo contendere, the court fined him $200, suspended the imposition of a jail sentence, and placed him on probation for 2 years.

4105. Misbranding of amphetamine sulfate tablets and dextro-amphetamine hydrochloride tablets. U. S. v. Charles R. Wirth (Wirth's Drug Store). Plea of nolo contendere. Fine of $900 and sentence of 18 months in jail. Jail sentence suspended and defendant placed on probation for 3 years. (F. D. C. No. 34849. Sample Nos. 67131–L, 67133–L, 67134–L.)

INFORMATION FILED: June 12, 1953, Eastern District of Louisiana, against Charles R. Wirth, trading as Wirth's Drug Store, New Orleans, La.

NATURE OF CHARGE: On or about November 25 and December 9 and 16, 1952, while a number of *amphetamine sulfate tablets* and *dextro-amphetamine hydrochloride tablets* were being held for sale at Wirth's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer the drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: July 8, 1953. A plea of nolo contendere having been entered, the court fined the defendant $900 and sentenced him to serve 18 months in jail. The jail sentence was suspended, and the defendant was placed on probation for 3 years.

4106. Misbranding of dextro-amphetamine sulfate tablets, methyltestosterone tablets, and pentobarbital sodium capsules. U. S. v. Rollin P. Middlebrooks (Middlebrooks Pharmacy). Plea of guilty. Fine, $50. (F. D. C. No. 34871. Sample Nos. 2358–L, 2361–L, 2368–L, 2373–L, 2457–L.)

INFORMATION FILED: September 15, 1953, Middle District of Georgia, against Rollin P. Middlebrooks, trading as Middlebrooks Pharmacy, Macon, Ga.

NATURE OF CHARGE: On or about October 21 and 27 and November 7 and 12, 1952, while a number of *dextro-amphetamine sulfate tablets*, *methyltestosterone*

tablets, and *pentobarbital sodium capsules* were being held for sale at Middlebrooks Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer the drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: September 29, 1953. The defendant having entered a plea of guilty, the court fined him $50.

4107. Misbranding of pentobarbital sodium capsules. U. S. v. Harry Goldstein (Nu Cedar Pharmacy). Plea of nolo contendere. Fine, $300. (F. D. C. No. 34339. Sample Nos. 25785–L to 25787–L, incl.)

INFORMATION FILED: April 20, 1953, Eastern District of Pennsylvania, against Harry Goldstein, trading as Nu Cedar Pharmacy, Philadelphia, Pa.

NATURE OF CHARGE: On or about July 10, 15, and 23, 1952, while quantities of *pentobarbital sodium capsules* were being held for sale at the Nu Cedar Pharmacy, after shipment in interstate commerce, the defendant caused a number of the capsules to be dispensed upon requests for refills of a written prescription, without obtaining authorization by the prescribing physician. This act of dispensing was contrary to Section 503 (b) (1), and resulted in the capsules so dispensed being misbranded while held for sale.

DISPOSITION: May 18, 1953. The defendant having entered a plea of nolo contendere, the court fined him $300.

4108. Misbranding of pentobarbital sodium capsules. U. S. v. Oneida Medical Center Pharmacy, Inc. Plea of nolo contendere. Fine, $200. (F. D. C. No. 34312. Sample No. 55278–L.)

INFORMATION FILED: April 3, 1953, Northern District of New York, against Oneida Medical Center Pharmacy, Inc., Oneida, N. Y.

NATURE OF CHARGE: On or about September 11, 1952, while a number of *pentobarbital sodium capsules* were being held for sale at the Oneida Medical Center Pharmacy, Inc., after shipment in interstate commerce, the defendant caused a number of the capsules to be dispensed without a prescription from a practitioner licensed by law to administer the drug. This act of dispensing was contrary to Section 503 (b) (1), and resulted in the drug so dispensed being misbranded while held for sale.

DISPOSITION: June 3, 1953. The defendant having entered a plea of nolo contendere, the court fined it $200.

4109. Misbranding of Seconal Sodium capsules and tablets containing a mixture of sulfadiazine, sulfamerazine, sulfamethazine, and penicillin-G. U. S. v. Otto Strickland (Strickland Drug Store). Plea of guilty. Fine, $200. (F. D. C. No. 34812. Sample Nos. 61119–L, 61120–L, 61122–L, 61123–L.)

INFORMATION FILED: April 14, 1953, Eastern District of Oklahoma, against Otto Strickland, trading as the Strickland Drug Store, Atoka, Okla.

NATURE OF CHARGE: On or about October 2, 3, and 6, 1952, while a number of *Seconal Sodium capsules* and *tablets containing a mixture of sulfadiazine, sulfamerazine, sulfamethazine, and penicillin-G* were being held for sale at the Strickland Drug Store, after shipment in interstate commerce, the defendant caused a number of the tablets and capsules to be dispensed without a prescription from a practitioner licensed by law to administer the drugs. This

act of dispensing was contrary to Section 503 (b) (1), and resulted in the drugs being misbranded while held for sale.

DISPOSITION: May 13, 1953. The defendant having entered a plea of guilty, the court fined him $200.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4110. Misbranding of amphetamine sulfate tablets. U. S. v. Samuel Swartz (Sam's Cut Rate Drugs), and Chester J. Marciniak and Ralph E. Pickard. Pleas of nolo contendere. Fine of $75 against each defendant; fines against Defendants Marciniak and Pickard suspended. (F. D. C. No. 34813. Sample Nos. 12082–L, 12724–L, 12730–L.)

INFORMATION FILED: April 23, 1953, Northern District of Ohio, against Samuel Swartz, trading as Sam's Cut Rate Drugs, Toledo, Ohio, and Ralph E. Pickard, manager, and Chester J. Marciniak, a pharmacist.

ALLEGED VIOLATION: On or about March 12, 13, and 19, 1952, while a number of *amphetamine sulfate tablets* were being held for sale at Sam's Cut Rate Drugs, after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the repackaged tablets were fabricated from two or more ingredients, and their label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use.

DISPOSITION: April 23, 1953. Pleas of nolo contendere having been entered, the court fined each defendant $75, but suspended the fines against Defendants Marciniak and Pickard.

4111. Misbranding of dextro-amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. College Avenue Pharmacy and J. Homer Thompson and Hoyt A. Thompson. Pleas of nolo contendere. Fine of $150 against each defendant. Individual defendants also placed on probation for 2 years. (F. D. C. No. 34310. Sample Nos. 757–L, 1741–L, 1746–L, 1754–L, 1758–L, 1759–L, 2002–L.)

INFORMATION FILED: March 27, 1953, Northern District of Georgia, against the College Avenue Pharmacy, a partnership, Decatur, Ga., and J. Homer Thompson and Hoyt A. Thompson, partners in the partnership.

ALLEGED VIOLATION: On or about November 18 and December 9, 13, and 24, 1951, and January 7, 8, and 14, 1952, while a number of *dextro-amphetamine sulfate tablets* and *Seconal Sodium capsules* were being held for sale at the College Avenue Pharmacy, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: April 17, 1953. Pleas of nolo contendere having been entered by the defendants, the court fined each defendant $150. In addition, the court placed each individual defendant on probation for 2 years.

4112. Misbranding of Blue Ridge dry mineral water. U. S. v. 44 Cartons * * *. (F. D. C. No. 34909. Sample No. 64840–L.)

LIBEL FILED: March 23, 1953, Northern District of Iowa.

ALLEGED SHIPMENT: On or about July 30, 1952, by the Blue Ridge Minerals Co., from Chicago, Ill.

PRODUCT: 44 cartons of *Blue Ridge dry mineral water* at Waterloo, Iowa. Examination showed that the product was a mixture of epsom salt, table salt (sodium chloride), sodium bicarbonate, and calcium carbonate.

LABEL, IN PART: (Carton) "Blue Ridge Dry Mineral Water A Combination of Natural Minerals To Add To Your Drinking Water Analysis Of Contents Magnesium Sulphate, Calcium Carbonate, Sodium Bi-carbonate, Sodium Chloride. Net Weight One-Half Pound."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Dry Mineral Water * * * A Combination of Natural Minerals * * * How To Make Your Own Mineral Water * * * Drink Blue Ridge Mineral Water" were false and misleading since the article was not a dry mineral water or a combination of natural minerals and would not make a mineral water when used as directed.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of arthritis, kidney, liver, and stomach disorders, and high blood pressure, which were the conditions for which the article was recommended in advertising sponsored by the distributor, the Blue Ridge Minerals Co.

DISPOSITION: April 23, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4113. Adulteration and misbranding of sodium chloride. U. S. v. 11 Sacks, etc. (F. D. C. No. 34660. Sample No. 54968–L.)

LIBEL FILED: February 16, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 15, 1952, from Port Huron, Mich.

PRODUCT: 11 50-pound sacks and 1 40-pound sack of *sodium chloride* at Chicago, Ill.

RESULTS OF INVESTIGATION: The product was delivered to Arthur S. LaPine & Co., after arrival at Chicago, and was repackaged by that firm into 50-pound plastic sacks bearing the label described below.

LABEL, IN PART: (Sack) "50 Pounds Sodium Chloride U. S. P. Granular contents intended for laboratory or manufacturing use Distributed by Arthur S. LaPine Company * * * Chicago 29, Illinois."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sodium Chloride," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its purity and quality fell below, the official standard. The standard requires that dried sodium chloride contains not less than 99.5 percent NaCl and that not more than a trace of calcium compounds is present. The article, after drying, contained less than 99.5 percent NaCl, namely, 98.8 percent and the remainder of the product consisted largely of calcium phosphate.

Misbranding, Section 502 (a), the label statement "Sodium Chloride U. S. P." was false and misleading as applied to a product which failed to conform to the requirements of the United States Pharmacopeia.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 27, 1953. Default decree of condemnation and destruction.

4114. Adulteration and misbranding of Succidol capsules. U. S. v. 2 Bottles * * *. (F. D. C. No. 34782. Sample No. 41274–L.)

LIBEL FILED: March 27, 1953, Western District of Washington.

ALLEGED SHIPMENT: On or about December 11, 1952, by the Calvital Co., Inc., from Mount Vernon, N. Y., to Los Angeles, Calif., and from there to Orting, Wash., by the J. K. Hornbein Co.

PRODUCT: 2 bottles of *Succidol capsules* at Orting, Wash.

LABEL, IN PART: (Bottle) "1000 Succidol Capsules Each Capsule Contains: * * * Para-Aminobenzoic Acid As The Sodium Salt 3 Gr."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 3 grains of para-aminobenzoic acid as the sodium salt, per capsule.

Misbranding, Section 502 (a), the label statement "Each Capsule Contains: * * * Para-Aminobenzoic Acid As The Sodium Salt 3 Gr." was false and misleading as applied to the article, which contained less than 3 grains of para-aminobenzoic acid as the sodium salt, per capsule.

DISPOSITION: June 2, 1953. Default decree of condemnation and destruction.

4115. Adulteration of clinical thermometers. U. S. v. 221 Thermometers * * *. (F. D. C. No. 34677. Sample No. 20135–L.)

LIBEL FILED: February 20, 1953, District of Minnesota.

ALLEGED SHIPMENT: On or about December 29, 1952, by the Hygrade Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 221 *clinical thermometers* at Minneapolis, Minn. The thermometers were packed in 6-unit packages. Examination of 24 thermometers revealed that 3 failed to comply with the requirement for accuracy of reading specified in CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in CS1–52.

LABEL, IN PART: (Engraved on thermometer) "1234 [or other numbers] * * * Rectal"; (inserts in 6-unit package) "Certificate of Accuracy For Clinical Thermometer No. * * * Date of Test Dec. 1952 This Certifies that the enclosed thermometer bearing the above identification number has been tested on the above date and is correct. This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards,

Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1–52 Department of Commerce)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess since it failed to comply with the requirement for accuracy of reading specified in CS1–52.

DISPOSITION: June 19, 1953. Default decree of destruction.

4116. Adulteration and misbranding of clinical thermometers. U. S. v. 67 Dozen * * * (and 1 other seizure action). (F. D. C. Nos. 34889, 34890. Sample Nos. 39762–L, 73131–L.)

LIBELS FILED: March 13 and 20, 1953, Eastern District of Pennsylvania and Southern District of California.

ALLEGED SHIPMENT: On or about November 21, 1952, and January 9 and 16, 1953, by the Hygrade Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 67 dozen *rectal thermometers* at Philadelphia, Pa., and 6 dozen *oral thermometers* at Los Angeles, Calif.

Examination disclosed that 7 rectal thermometers of 24 tested and 4 oral thermometers of 23 tested failed to comply with the specifications established in the National Bureau of Standards' Commercial Specifications 1–52 applicable to such thermometers. 6 rectal thermometers failed to comply with the requirement for accuracy, and 1 rectal thermometer failed to comply with the entrapped gas test. The defects of the oral thermometers were as follows: 1 thermometer failed to comply with the standard for accuracy; 2 thermometers failed to comply with the test for retreating index; and 1 thermometer failed to comply with the test for ease of shaking down the mercury column (hard shaker).

LABEL, IN PART: "One Fever Thermometer Kind—Rectal" and "Hygrade Oral."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the articles fell below that which they purported and were represented to possess since they failed to comply with the specifications established in the National Bureau of Standards' Commercial Specifications 1–52.

Misbranding, Section 502 (b) (1), the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: April 24 and May 5, 1953. Default decrees of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4117. Misbranding of okra tablets. U. S. v. 24 Bottles, etc. (F. D. C. No. 34875. Sample No. 57534–L.)

LIBEL FILED: March 3, 1953, District of Columbia.

ALLEGED SHIPMENT: On or about February 13, 1953, by the Daland Vitamin Co., from Wilmington, Del.

PRODUCT: 24 25-tablet bottles and 11 100-tablet bottles of *okra tablets* at Washington, D. C.

*See also Nos. 4112–4114.

LABEL, IN PART: (Bottle) "Daland's Okra Tablets Dehydrated Concentrate of Natural Okra, finely ground. Mild Vanilla Flavor * * * Directions: * * * In minor peptic irritations, minor peptic ulcerations of stomach or intestines, the number of tablets can be regulated per meal according to size of meal and as relief from food roughage irritation dictates. Okra is a vegetable, and a natural source of food minerals and chlorophyl. It adds smoothage to food bulk, thereby forming a softer consistency on the walls of stomach and intestines, lessening irritations of food roughage especially on peptic irritations. Okra is soothingly and mildly alkaline."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for stomach and intestinal ulcers and irritation, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: April 30, 1953. Default decree of condemnation and destruction.

4118. Misbranding of radioactive mineral. U. S. v. 79 Bags, etc. (F. D. C. No. 34667. Sample No. 41040–L.)

LIBEL FILED: February 18, 1953, Eastern District of Washington.

ALLEGED SHIPMENT: On or about October 25, 1952, by Radon Supply, from Boulder, Mont.

PRODUCT: 29 5-pound unlabeled bags and 50 5-pound labeled bags of *radioactive mineral* at Spokane, Wash., together with a number of leaflets entitled "Now! You May Test the Healing Effects of the Gamma Rays of Uranium Ore In Your Own Home."

Examination showed that the bags contained a gray-colored coarsely powdered ore which emitted a very weak radioactivity, principally gamma rays. The amount of gamma rays emitted was much less than that emitted by the luminous dial of an ordinary wrist watch.

LABEL, IN PART: (Bag) "Radioactive Mineral from Boulder Uranium Area Famous Health Mines Radon Supply."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflet were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for various forms of arthritis, rheumatism, muscular ailments, calcium stiffened joints, hay fever, sinus trouble, eczema, unusual disease or disorder, etc., and that the article would restore and rejuvenate cells and glands. The article would not be an effective treatment for those conditions.

DISPOSITION: May 16, 1953. Default decree of condemnation and destruction.

4119. Misbranding of radioactive ore device. U. S. v. 3 Metal Cabinet Treating Units, etc. (F. D. C. No. 34616. Sample No. 40629–L.)

LIBEL FILED: February 10, 1953, Western District of Washington.

ALLEGED SHIPMENT: On or about November 1, 1952, by the C. & J. Rental Service, from Great Falls, Mont.

PRODUCT: 3 metal cabinet treating units known as *radioactive ore devices*, 1 knocked down 3-shelf metal stand, and 1 Geiger counter at Seattle, Wash., together with 2 reprints of one of the pages of the July 13, 1952, issue of a Montana newspaper and a number of testimonial letters relating to the device.

Examination indicated that the treating unit contained an ore, emitting

very weak radioactivity which was much less than that emitted by the luminous dial of an ordinary wrist watch.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, consisting of the accompanying reprints and testimonials, contained false and misleading statements. The statements represented and suggested that the article was effective in the treatment of various forms of arthritis, rheumatism, sciatica, and bursitis, whereas the article was not effective in the treatment of such conditions.

DISPOSITION: June 29, 1953. Default decree of forfeiture. The court ordered that the treating unit, the metal stand, and the Geiger counter be loaned to the Food and Drug Administration for ten days and thereafter be destroyed, and that the labeling be destroyed also. On or about July 3, 1953, the decree was amended to permit the Food and Drug Administration to retain the Geiger counter as its property.

4120. Misbranding of Radiant Ozone Generator. U. S. v. 2 Devices * * *. (F. D. C. 35232. Sample Nos. 42572–L, 42573–L.)

LIBEL FILED: May 21, 1953, Northern District of California.

ALLEGED SHIPMENT: On or about January 21 and during July 1952, by William Hartline, from Eldorado Springs, Mo.

PRODUCT: 2 *Radiant Ozone Generators* at Seaside, Calif. The devices consisted essentially of a series of tubes, which were similar to neon tubes, with connections for attachment to a source of electric current.

LABEL, IN PART: "Radiant Ozone Generator Patent No. 2328640 2031 Main St., Kansas City, Mo."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device, namely, 41 pages of testimonial letters and a leaflet entitled "Color," which were enclosed in the shipping container of one of the devices, were false and misleading. The statements represented and suggested that the device constituted an adequate and effective means for the treatment of inflammation of the kidneys, neuritis, neuralgia, blood clots, colds, diabetes, sinus trouble, headaches, nervousness, arthritis, sciatic rheumatism, asthma, heart trouble, kidney trouble, boils, poison oak, varicose veins, abnormal blood pressure, stomach cancer, stiff joints, breast cancer, appendicitis, chickenpox, colitis, toxic headaches, high blood pressure, enlarged heart, pleurisy, angina pectoris, asthma, pneumonia, sprains, throat trouble, bruise, cataracts, bloat, eczema, wens, broken bones, liver trouble, stomach trouble, gland trouble, bronchial trouble, rundown condition, cancerous growth, catarrh, constipation, watering eyes, pernicious anemia, paralysis, sore throat, piles, and ear ailment. The device did not constitute an adequate and effective means for the treatment of such conditions.

DISPOSITION: October 7, 1953. Default decree of condemnation and destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1934

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4121–4140

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 26, 1954.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 4125, 4128, 4131, 4138, 4140; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4125, 4126, 4131; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4126, 4128, 4131; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 4130.

297270—54——1

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4121. Misbranding of Isopto Alkaline. U. S. v. 26 Cartoned Bottles * * *. (F. D. C. No. 34907. Sample No. 67271–L.)

LIBEL FILED: March 20, 1953, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about December 26, 1952, by Alcon Laboratories, Inc., from Fort Worth, Tex.

PRODUCT: 26 cartoned bottles of *Isopto Alkaline* at New Orleans, La. Examination showed that the product was contaminated with *Pseudomonas aeruginosa.*

LABEL, IN PART: (Bottle) "15 cc. Isopto Alkaline Alcon Brand Of Physiologic Methyl Cellulose Ophthalmic 1% with Benzalkonium Chloride 1:50,000 in saline solution INDICATIONS: As a vehicle for Ophthalmic drugs, which are stable in an alkaline (pH 7.4) menstruum. Directions: One to two drops in eye(s) three times daily, or as directed by Physician."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, namely, as a vehicle for ophthalmic drugs, used 3 times daily.

DISPOSITION: May 4, 1953. Default decree of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4122. Misbranding of dextro-amphetamine sulfate tablets and secobarbital sodium capsules. U. S. v. Clyde King (Clyde King Drug Co.), and Benjamin H. Darnell. Pleas of guilty. Fine of $50 against each defendant. (F. D. C. No. 34841. Sample Nos. 46279–L to 46283–L, incl., 46285–L.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against Clyde King, trading as the Clyde King Drug Co., Birmingham, Ala., and Benjamin H. Darnell, a pharmacist for the company.

NATURE OF CHARGE: On or about July 18, 21, 26, 28, and 29, 1952, while a number of *dextro-amphetamine sulfate tablets* and *secobarbital sodium capsules* were being held for sale at the Clyde King Drug Co., after shipment in interstate commerce, various quantities of these drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

Clyde King was charged as a defendant in each of the 6 counts of the information, and Benjamin H. Darnell was joined as a defendant in 3 of the counts.

DISPOSITION: May 25, 1953. The defendants having entered pleas of guilty, the court fined each defendant $50.

4123. Misbranding of dextro-amphetamine sulfate tablets and methyltestosterone tablets. U. S. v. Holt Chapman (Chapman's Pharmacy). Plea of guilty. Fine of $50. (F. D. C. No. 34872. Sample Nos. 2456–L, 2640–L, 2644–L, 2649–L, 2656–L.)

INFORMATION FILED: September 15, 1953, Middle District of Georgia, against Holt Chapman, trading as Chapman's Pharmacy, Macon, Ga.

NATURE OF CHARGE: On or about October 22, 27, and 31, and November 12, 1952, while a number of *dextro-amphetamine sulfate tablets* and *methyltestosterone*

tablets were being held for sale at Chapman's Pharmacy, after shipment in interstate commerce, the defendant caused a number of these tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: September 29, 1953. The defendant having entered a plea of guilty, the court imposed a fine of $50.

4124. Misbranding of Amytal Sodium capsules, dextro-amphetamine sulfate tablets, amphetamine sulfate tablets, and methyltestosterone tablets. U. S. v. Drive-In Drug Store, a partnership, and Dale E. Dunn and Ralph C. Dunn. Pleas of guilty. Fine of $1,500 against partnership; sentence of 1 year in jail against each individual suspended. (F. D. C. No. 34864. Sample Nos. 13812–L, 14562–L, 14565–L, 14570–L, 14571–L, 14575–L.)

INFORMATION FILED: On or about May 21, 1953, District of Utah, against the Drive-In Drug Store, a partnership, Salt Lake City, Utah, and Dale E. Dunn, a partner in the partnership, and Ralph C. Dunn, an employee of the partnership.

NATURE OF CHARGE: On or about September 19 and 29 and October 5, 14, and 22, 1952, while a number of *Amytal Sodium capsules*, *dextro-amphetamine sulfate tablets*, *amphetamine sulfate tablets*, and *methyltestosterone tablets* were being held for sale at the Drive-In Drug Store, after shipment in interstate commerce, various quantities of these drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

The partnership was charged in each of the six counts of the information with causing the dispensing of the drugs involved; Dale E. Dunn was joined as a defendant in count 4 relating to the dispensing of a quantity of *dextro-amphetamine sulfate tablets*, and Ralph C. Dunn was joined as a defendant in the other counts of the information.

DISPOSITION: Pleas of guilty having been entered, the court, on June 27, 1953, fined the partnership $6,000 and sentenced each individual to 1 year in jail. On July 10, 1953, following a hearing on a motion for a reduction of the sentence, the court reduced the fine against the partnership to $1,500 and suspended the jail sentence previously imposed against the individual defendants.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4125. Misbranding of sulfisoxazole tablets. U. S. v. Morris H. Bernett (Rex Drugs), and George C. Hoss. Plea of not guilty by Defendant Bernett and plea of guilty by Defendant Hoss. Tried to the court. Verdict of not guilty as to Defendant Bernett. Fine of $50 against Defendant Hoss. (F. D C. No. 33732. Sample No. 26256–L.)

INFORMATION FILED: November 13, 1952, Eastern District of Pennsylvania, against Morris H. Bernett, trading as Rex Drugs, Philadelphia, Pa., and George C. Hoss, an employee.

ALLEGED VIOLATION: On or about January 19, 1952, while a number of *sulfisoxazole tablets* were being held for sale at Rex Drugs, after shipment in

interstate commerce, the defendants caused a number of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the tablets failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), the tablets were fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1) and (2), the labeling of the tablets failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: A plea of guilty was entered by Defendant Hoss and a plea of not guilty by Defendant Bernett. The case against Defendant Bernett came on for trial before the court on September 23, 1953, and at the conclusion of the testimony, the court returned a verdict of not guilty with respect to this defendant. Upon the basis of Defendant Hoss' plea of guilty, the court fined him $50 on September 23, 1953.

4126. Misbranding of sulfadiazine tablets, methamphetamine hydrochloride tablets, and dextro-amphetamine sulfate tablets. U. S. v. Walter Glen Huffman (Economy Drug Store). Plea of nolo contendere. Fine, $75. (F. D. C. No. 34815. Sample Nos. 11939–L, 12377–L, 12731–L.)

LIBEL FILED: April 23, 1953, Northern District of Ohio, against Walter Glen Huffman, trading as the Economy Drug Store, Toledo, Ohio.

ALLEGED VIOLATION: On or about March 13 and 17, 1952, while a number of *sulfadiazine tablets*, *methamphetamine hydrochloride tablets*, and *dextro-amphetamine sulfate tablets* were being held for sale at the Economy Drug Store, after shipment in interstate commerce, the defendant caused one bottle of *methamphetamine hydrochloride tablets* to be dispensed in the original bottle in which such tablets had been shipped in interstate commerce, without the prescription of a physician, and caused also various quantities of the other drugs to be repacked and dispensed without prescriptions, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *methamphetamine hydrochloride tablets* failed to bear adequate directions for use (the bottle in which the tablets had been shipped in interstate commerce bore no directions for use since it was exempt from such requirements by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendant in causing the dispensing of the drug without a physician's prescription caused the exemption to expire).

Further misbranding, Section 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 23, 1953. The defendant having entered a plea of nolo contendre, the court fined him $75.

4127. Misbranding of Bi-Lets tablets. U. S. v. 1 Bottle, etc. (F. D. C. No. 34877. Sample No. 57113–L.)

LIBEL FILED: March 6, 1953, Southern District of Ohio.

ALLEGED SHIPMENT: On or about October 15, 1952, from Buffalo, N. Y.

PRODUCT: 1 bottle of *Bi-Lets tablets*, 3 cellophane envelopes containing 4 tablets, 500 empty boxes labeled, in part, "Bi-Lets," and 400 circulars entitled "Read This For Your Health's Sake!" at Cincinnati, Ohio, in the possession of Medical Laboratories.

RESULTS OF INVESTIGATION: The bottle containing the *Bi-Lets tablets* was shipped in interstate commerce as described above, and after receipt by Medical Laboratories, a portion of the tablets in the bottle was repackaged into small cellophane envelopes of 4 tablets each. The envelopes then were attached to the above-mentioned circular and distributed by the consignee as free samples. Upon request from customers desiring to purchase tablets, the consignee would repackage the remaining tablets into the empty boxes.

LABEL, IN PART: (Box) "Bi-Lets For Your Health Distributed By Medical Laboratories Room 402—104 W. 4th Street Cincinnati 2, Ohio Contents 25 Tablets Directions: Take one (1) or one-half (½) Bi-Let at bedtime. In obstinate cases, take one (1) at bedtime and one (1) before breakfast. Caution: In any condition where there has been abdominal pain and vomiting you should see a physician. Formula: Extract cascara sagrada 2 gr., Phenolphthalein 1 gr., Aloin ⅛ gr., Extract Nux Vomica ⅛ gr. (Strychnine 0.009 gr.) Oxgall 1 gr."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "For Your Health" appearing on the box label and certain statements in the above-mentioned circular accompanying the article were false and misleading. The statements represented and suggested that the article would be necessary "For Your Health"; that disorders of the liver, gallbladder, and intestinal tract cause constipation and other ailments; and that the article was an adequate and effective treatment for such conditions and for overindulgence. The article would not be necessary "For Your Health," and it was not an adequate and effective treatment for the conditions stated and implied, including overindulgence.

Further misbranding, Section 502 (f) (1) and (2), the labeling of the article, namely, the box labeling, failed to bear adequate directions for use; and the box labeling and the above-mentioned circular failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form, as are necessary for the protection of users. The box label did not bear indications for use of the article; and the box label and the circular did not bear adequate warnings against use of the article when symptoms of appendicitis were present, where a skin rash would appear, and against frequent or continued use to prevent formation of the laxative habit. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: April 20, 1953. Default decree of condemnation and destruction.

4128. Adulteration and misbranding of Carbolatum salve. U. S. v. 193 Jars, etc. (F. D. C. No. 34612 Sample Nos. 3020–L, 3021–L.)

LIBEL FILED: January 26, 1953, District of Columbia.

ALLEGED SHIPMENT: On or about June 11, July 23, and August 11, 1952, by the Windsor Chemical Laboratories, from Philadelphia, Pa.

PRODUCT: 193 4-ounce jars and 165 14-ounce jars of *Carbolatum salve* at Washington, D. C. Analysis showed that the product in the 4-ounce jars contained not more than 1.55 percent of phenol and that the article in the 14-ounce jars contained not more than 0.67 percent of phenol. The National Formulary specifies that carbolic acid ointment contains not less than 1.8 percent of phenol.

LABEL, IN PART: (Jar) "Fleming's Carbolatum Salve for Man and Beast * * * Instructions: Carefully sooth injured member with warm water and apply Carbolatum twice a day as required. * * * For skin irritation mix one part Sulphur with four parts Carbolatum and use daily."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Carbolic Acid Ointment," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard since it contained a smaller proportion of phenol than the minimum specified in the National Formulary.

Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not an effective treatment for such conditions: "Carbolatum * * * soothes skin surface pains. For skin irritation mix one part Sulphur with four parts Carbolatum and use daily. For The Family A Great aid for * * * Bruises * * * and Irritated Skin * * * For Animals Skin Eruptions * * * Cow Pox." Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe dosage and methods of application, in such manner and form, as are necessary for the protection of users since it contained phenol; and the labeling of the article failed to bear a warning against application to large areas of the body or against its use under a bandage on fingers or toes.

DISPOSITION: June 2, 1953. Default decree of condemnation. The court ordered that the product be delivered to a local hospital for its use and not for sale. The product was to be used in the maintenance department of the hospital, for machinery lubrication.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4129. Adulteration and misbranding of Cal-D-Fer tablets and tablets of mannitol hexanitrate with phenobarbital and adulteration of triple sulfa tablets. U. S. v. Shaw Pharmacal Co. Plea of guilty. Fine, $800. (F. D. C. No. 33766. Sample Nos. 11202–L, 12527–L, 31191–L.)

INFORMATION FILED: March 19, 1953, Eastern District of Missouri, against the Shaw Pharmacal Co., a corporation, St. Louis, Mo.

*See also No. 4128.

ALLEGED VIOLATION: On or about August 15 and September 17, 1951, the defendant caused a number of *Cal-D-Fer tablets* and *triple sulfa tablets* to be introduced and delivered for introduction into interstate commerce, at St. Louis, Mo., for delivery into the State of Ohio.

On or about May 22, 1951, the defendant gave to a firm engaged in the business of shipping drugs in interstate commerce, at St. Louis, Mo., an invoice containing a guaranty to the effect that no article listed in the invoice was adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On or about May 22, 1951, the defendant caused to be delivered to the holder of the guaranty, at St. Louis, Mo., a number of *tablets of mannitol hexanitrate with phenobarbital*, which were covered by the guaranty and which were adulterated and misbranded.

NATURE OF CHARGE: *Cal-D-Fer tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess in that each tablet of the article was represented to contain 5 grains of calcium phosphate (dibasic), whereas each tablet of the article contained less than 5 grains of calcium phosphate (dibasic). Misbranding, Section 502 (a), the label statement "Each tablet contains * * * Calcium Phosphate (dibasic) 5 gr." was false and misleading.

Triple sulfa tablets. Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess in that the article was represented to supply to the body from each tablet 2.56 grains of sulfadiazine, 2.56 grains of sulfamerazine, and 2.56 grains of sulfamethazine, whereas the article would not supply to the body from each tablet such amounts of sulfadiazine, sulfamerazine, and sulfamethazine since the tablets would not completely disintegrate and thus part of each tablet would pass through the body, would be eliminated, and would not be used by the body.

Tablets of mannitol hexanitrate with phenobarbital. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet was represented to contain ¼ grain of phenobarbital and ½ grain of mannitol hexanitrate, whereas each tablet contained less than ¼ grain of phenobarbital and less than ½ grain of mannitol hexanitrate. Misbranding, Section 502 (a), the label statement "Each tablet contains: Phenobarbital ¼ gr. * * * Mannitol Hexanitrate ½ gr." was false and misleading.

DISPOSITION: September 28, 1953. The defendant having entered a plea of guilty, the court fined it $800.

4130. Adulteration of iodophthalein, Ringer's solution tablets, ammoniated mercury ointment, and Atabrine Dihydrochloride, and adulteration and misbranding of quinine phosphate. U. S. v. 9,000 Bottles, etc. (F. D. C. No. 34914. Sample Nos. 43981–L, 43985–L, 43987–L to 43989–L, incl., 44151–L, 44155–L to 44158–L, incl., 44162–L, 44163–L.)

LIBEL FILED: March 30, 1953, District of Kansas.

ALLEGED SHIPMENT: During the month of August 1952, by Chemical Commodities, Inc., from Kansas City, Mo.

PRODUCT: 9,000 100-gram bottles of *iodophthalein*, 1,000 100-tablet bottles of *Ringer's solution tablets*, 2,000 1-pound jars of *ammoniated mercury ointment*, 33 4-ounce jars of *quinine phosphate*, and 23 pounds of *Atabrine Dihydrochloride* contained in 1 unlabeled drum but originally shipped in 4-ounce bottles, at Olathe, Kans.

Examination showed that the *iodophthalein* contained insoluble material; that the caking and disintegrating of *Ringer's solution tablets* had rendered them unsuitable for their intended use of supplying an accurate amount of the salts contained in them, so that it was not possible to prepare Ringer's solution for injection by dilution of the tablets in accordance with the label directions; that the *ammoniated mercury ointment* in many of the jars had separated from the ointment base and settled to the bottom of the jars, so that the article was not uniform in composition; that the *quinine phosphate* showed evidence of fire and water damage, with the labels being largely obliterated by stains, abrasion, and soiling, and the bottles containing black, charred material under the caps; and that the *Atabrine Dihydrochloride* in its original containers showed evidence of fire damage, with the bulk material transferred from the original containers to the drum being contaminated with wood splinters, rust flakes, and other extraneous material.

NATURE OF CHARGE: *Iodophthalein.* Adulteration, Section 501 (b), the article purported to be and was represented as "Iodophthalein," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since it contained insoluble material.

Ringer's solution tablets. Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess.

Ammoniated mercury ointment. Adulteration, Section 501 (b), the article purported to be and was represented as "Ammoniated Mercury Ointment," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the official standard since the article was not of uniform composition.

Quinine phosphate. Adulteration, Section 501 (b), the article purported to be and was represented as "quinine phosphate," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it contained added foreign substances. Misbranding, Section 502 (c), the information required by Section 502 (b) to appear on the label of the *quinine phosphate* was not prominently placed thereon with such conspicuousness (as compared with other words and statements on the label) and in such terms as to render such information likely to be read by the ordinary individual under customary conditions of purchase and use since such information had become illegible by reason of fire, water, or other damage to the labels.

Atabrine Dihydrochloride. Adulteration, Section 501 (b), the article purported to be and was represented as "Quinacrine Hydrochloride," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since it contained added foreign substances. The *Atabrine Dihydrochloride* was alleged to be adulterated when introduced into, while in, and while held for sale after shipment in, interstate commerce; the *quinine phosphate* was alleged to be adulterated and misbranded while held for sale after shipment in interstate commerce; and the other products were alleged to be adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: May 14, 1953. Default decree of condemnation and destruction.

4131. Adulteration and misbranding of first aid kits. U. S. v. 414 First Aid Kits * * *. (F. D. C. No. 34465. Sample No. 69257–L.)

LIBEL FILED: January 6, 1953, District of Colorado.

ALLEGED SHIPMENT: On or about November 13, 1952, by the E. D. Bullard Co., from San Francisco, Calif.

PRODUCT: 414 *first aid kits*, consisting of a metal case with a hinged lid and containing first aid supplies at Denver, Colo.

The kits contained, among other items, an unlabeled glass ampul covered with a mesh cloth and a tube of ointment. Analysis of the contents of the glass ampul showed that it contained ammonia, a red color, and aromatic substances. Analysis of the ointment showed that it contained less than the declared 1.5 percent of carbolic acid.

LABEL, IN PART: (Tube) "Carbolated Petrolatum (Carbolic Acid 1.5%) Kip, Inc. Los Angeles 21, Calif. ⅛-oz. Avoir."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the component of the article labeled, in part, "Carbolated Petrolatum" differed from that which it was represented to possess since it contained less than 1.5 percent of carbolic acid.

Misbranding, Section 502 (b) (1) and (2), the article contained in the unlabeled glass ampul failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (e) (2), the article in the ampul was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient.

DISPOSITION: May 21, 1953. Default decree of condemnation. The court ordered that the unlabeled glass ampuls and the tubes of ointment be removed from the first aid kits and destroyed, and that after such removal and destruction, the first aid kits be given to a Federal institution for its use and not for sale.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4132. Action for declaratory judgment or injunction. Research Laboratories, Inc., v. Robert E. Hannegan, et al. Complaint dismissed.

COMPLAINT FILED: On or about August 8, 1947, Research Laboratories, Inc., Portland, Oreg., plaintiff, filed a complaint in the United States District Court for the District of Columbia, against Robert E. Hannegan (Post Office Department), Watson B. Miller (Federal Security Agency), and Paul B. Dunbar (Food and Drug Administration).

NATURE OF CHARGE: It was alleged in the complaint, with respect to matters arising under the Federal Food, Drug, and Cosmetic Act, (1) that the Food and Drug Administration had initiated against a drug known as *Nue-Ovo* several libel for condemnation proceedings in the district courts during the period between 1929 and the time of filing the complaint; (2) that at least three "hearings" under Section 305 of the Act had been conducted by the Food and Drug Administration's representatives, which "hearings," it was alleged, were a means of further harassing the plaintiff and those associated with it; (3) that the Federal Trade Commission, between 1930 and 1935, conducted extensive investigation of the plaintiff's conduct, but no regulatory action

*See also Nos. 4127–4129.

was taken under the Federal Trade Commission Act; (4) that plaintiff's counsel, after the entry of a decree of condemnation in 1946 and during the pendency of an appeal therefrom, discovered an irregularity in the labeling of the drug, and thereupon the plaintiff revised the said labeling and literature; (5) that the plaintiff advised Defendant Dunbar, on April 8, 1947, of the revisions made and sought his advice and comment, but that defendant refused to discuss the said revisions with plaintiff's attorneys, giving as his reason that the Food and Drug Administration could not enter into such discussions so long as litigation respecting the product was in progress; and (6) that, on August 4, 1947, the Food and Drug authorities made a further seizure of plaintiff's product, which was stored in a warehouse and was not for sale, though technically misbranded.

PRAYER FOR RELIEF: That the defendants be ordered to come forward and state any and all objections they might have to plaintiff's product, its labeling, or literature, and that the court determine the merits of such objections that might be made; and that the defendants be restrained from taking further administrative or enforcement action under the Federal Food, Drug, and Cosmetic Act, or, in the alternative, that a judicial declaration be issued as to plaintiff's rights with respect to the distribution of its product.

DISPOSITION: A motion for dismissal of the complaint was filed on behalf of the Government, and, on December 18, 1947, the court handed down the following opinion in favor of the motion:

MCGUIRE, *Associate Justice:* "There is no justiciable controversy here. *Aetna Life Insurance Company* v. *Haworth et al.*, 300 U. S. 227–240, 241. *Helco* v. *McNutt*, 137 F. 2d 681, 683, 687.

"*Currin* v. *Wallace* (306 U. S. 1) can be distinguished. There, there was an actual controversy of a real and substantial character going to the constitutionality of the Tobacco Inspection Act (Aug. 13, 1935) as the Circuit Court held, which view the Supreme Court adopted.

"Here, however, no such definitiveness exists. The declaratory judgment is not a substitute for a new trial or for an appeal from a former judgment deciding identical issues or issues which the court believes were necessarily passed upon. Borchard: Declaratory Judgments, 355. Nor can the Federal Security Agency under guise of this remedy be compelled to give an advisory opinion in futuro or to place its nihil obstat on some contemplated labeling of the plaintiff's product—that is neither its established purpose or function.

"Again, infraction of Title 21, § 331 USCA is a criminal act (§ 333) and what the plaintiff here is actually seeking is an advisory opinion *in limine* as to the criminality or lack of criminality of its prospective sales activities.

"Motion to dismiss granted. Counsel will prepare proper order."

Pursuant to the above opinion, an order was entered on January 8, 1948, dismissing the complaint. Research Laboratories, Inc., as plaintiff, thereafter filed a motion to vacate the order of dismissal; and, on October 26, 1948, after consideration of the arguments of counsel, the court denied the motion.

4133. Misbranding of inorganic nutrient tablets, soya lecithin, dicalcium phosphate tablets, and calcium phytate tablets. U. S. v. Inorganic Bioelements, Inc., and John F. Wischhusen. Pleas of nolo contendere. Fine of $300 against each defendant. (F. D. C. No. 33751. Sample Nos. 7852–L, 7853–L, 18773–L, 18775–L.)

INFORMATION FILED: January 13, 1953, Northern District of Ohio, against Inorganic Bioelements, Inc., Cleveland, Ohio, and John F. Wischhusen, a director of the corporation.

ALLEGED SHIPMENT: On or about November 8, 1950, and February 23 and March 13, 1951, from the State of Ohio into the States of Pennsylvania, Illinois, and Iowa.

LABEL, IN PART: "Each Tablet Contains: Manganese Sulfate_____ 170 mg. Iron Sulfate _____ 10 mg. Cobalt Sulfate_____ 3 mg. Copper Sulfate_____ 1 mg. Zinc Sulfate_____ 1 mg. In combination with Lecithin Inorganic IBI Nutrient Tablets Designed to Complement the Diet With Essential Trace Elements Known to be Deficient in Several Major Diseases"; "IBI Soya Lecithin, Refined Edible, Oil Free"; "IBI Tablets Each Tablet Contains 7½ Grains Dicalcium Phosphate, Flavored (Calcium Phosphate Dibasic)"; and "Calcium IBI Phytate Calcium–Inositol–Hexaphosphate * * * Designed to Correct and Prevent Relative Deficiencies and their Consequences Each Tablet Contains 7½ Grains Calcium Phytate, Flavored."

NATURE OF CHARGE: *Inorganic nutrient tablets.* Misbranding, Section 502 (a), certain statements in the following labeling of the article, which accompanied the article, were false and misleading: a leaflet entitled "The Miracle of the Ozarks," a pamphlet entitled "Health vs Disease," a booklet entitled "Notes on Inorganic Bioelements, volume 1, number 1," a folder entitled "Bang's Disease and Undulant fever are due to Nutritional Deficiencies," a leaflet entitled "Good-by Bang's Disease," a leaflet entitled "What About Trace Minerals," a folder entitled "The Role of Manganese and Other Essential Elements in Life Processes," a leaflet entitled "Retail Price List," a copy of a letter of March 16, 1950, from Dr. Fred Loe to Dr. Ira Allison, a copy of a letter of October 19, 1950, from Dr. Leonard W. Kuttler to Dr. Ira Allison, copies of letters of November 29, 1950, and January 2, 1951, from Edward F. (Frank) Slavik, M. D., to Mr. J. F. Wischhusen, a copy of a letter of December 21, 1950, from Guerin Buonpane to Mr. J. F. Wischhusen, a letter of February 28, 1951, from J. F. Wischhusen to B. R. Reuscher, and an invoice No. 470 dated February 23, 1951, from Inorganic Bioelements, Inc., to B. R. Reuscher, bearing reference to "your order No. letter 20th F." The statements in the labeling represented and suggested that manganese, cobalt, and zinc are essential in human nutrition; that they are known to be deficient in several major diseases and are a first requisite for normal body functioning; that the article would correct and prevent deficiencies of manganese, cobalt, and zinc, and the consequences of such deficiencies; that manganese, cobalt, and zinc, as supplied by the article, are associated with gland secretions and enzyme activities and are concerned with growth, reproduction, and health; that cobalt, as supplied by the article, is required to regenerate and mature red blood cells, prevent anemia, and increase hemoglobin; that the article would form within the body antibiotics destructive to Brucella organisms of all types; and that the article would be an adequate and effective treatment for diabetes, brucellosis, Malta fever, undulant fever, tularemia, disorders resulting from abortion, allergies, splenic enlargements, vertigo, "much chronic illness," arthritis, asthma, hay fever, allergic dermatitis of the hands, heart diseases, fatigue, weakness, backache, joint and muscle pain, irritability, nervousness, insomnia, severe mental depression, gastric ulcers and other stomach troubles, repeated attacks of chills and fever, malaise, mastitis, caked breast, diabetes (mellitus and insipidus), Buerger's disease, arthritic conditions, sciatica, lumbago, bone fractures, Paget's disease, sterility, and all cases of malnutrition; that the article would depress pathogens responsible for various disorders; that the article would

be an adequate and effective treatment for headaches, pains behind the knees, loss of weight, loss of strength, anemia, intolerance to light, rheumatism, and influenza; that the article would prevent susceptibility to colds and sore throats and prevent easy tiring, chronic muscular ailments, mental depression, and discomforts of pregnancy; that its use by the pregnant woman would render delivery easy, the milk supply abundant, and the baby exceptionally alert, healthy, and energetic; and that the article would fill the user with "pep" and would supply the difference between disease and health. The statements were false and misleading since the need in human nutrition for manganese, cobalt, and zinc has not been established; manganese, cobalt, and zinc are not known to be deficient in several major diseases and are not a first requisite for normal body functioning; manganese, cobalt, and zinc, as supplied by the article, are not associated with gland secretions and enzyme activities concerned with growth, reproduction, and health; cobalt, as supplied by the article, is not required to regenerate and mature red blood cells, to prevent anemia, and to increase hemoglobin; and the article would not be effective for the diseases and conditions stated and implied, and it would not fulfill the promises of benefit stated and implied.

Soya lecithin. Misbranding, Section 502 (a), certain statements in a letter dated February 28, 1951, from John F. Wischhusen to B. R. Reuscher, and in a leaflet entitled "Retail Price List" and in a circular entitled "Oil Free Soybean Lecithin Edible," accompanying the article, were false and misleading. The statements represented and suggested that the article was a tonic; that it was an adequate and effective treatment for calcination of the spine and other parts of the skeleton, hardening of the arteries, high and low blood pressure, hypertension, psoriasis, and pulmonary troubles; and that the article would be effective in the prevention of fatty livers and would check tendencies toward arteriosclerosis. The article was not a tonic; it was not an adequate and effective treatment for the diseases and conditions represented; and it would not be effective for the purposes stated.

Dicalcium phosphate tablets. Misbranding, Section 502 (a), certain statements in a letter of November 9, 1950, from J. F. Wischhusen to C. W. Berger, and in an invoice dated November 8, 1950, accompanying the article, were false and misleading. The statements represented and suggested that the article would be adequate and effective in the treatment of polio, diabetes, and Buerger's disease. The article would not be adequate and effective in the treatment of such diseases.

Calcium phytate tablets. Misbranding, Section 502 (a), certain statements in an invoice dated March 13, 1951, accompanying the article, were false and misleading. The statements represented and suggested that the article would be adequate and effective in the prevention and treatment of polio and would effect steady improvement in the general health of the user. The article would not be adequate and effective in the prevention and treatment of polio, and it would not effect steady improvement in the general health of the user. The *calcium phytate tablets* were alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 15, 1953. The defendants having entered pleas of nolo contendere, the court fined each defendant $300.

4134. Misbranding of Raymor No. 50 capsules. U. S. v. 4 Bottles, etc. (F. D. C. No. 34879. Sample No. 33850–L.)

LIBEL FILED: March 11, 1953, Eastern District of Michigan; amended libel filed March 23, 1953.

ALLEGED SHIPMENT: On or about November 1, 1951, by the Raymor Food Products Co., from Chicago, Ill.

PRODUCT: 4 180-capsule bottles of *Raymor No. 50 capsules* at Jackson, Mich., together with a number of leaflets entitled "Professional Order Blank" and 1 copy each of 5 issues of a publication designated "Raymor Nutritional Review" distributed monthly by the Raymor Food Products Co. and dated March, May, June, November, and December, 1952.

Examination showed that the *Raymor No. 50 capsules* contained per 6 capsules not more than 164 milligrams of vitamin C, 0.16 milligram of iodine, 803 milligrams of calcium, and 381 milligrams of phosphorus.

LABEL, IN PART: "Raymor Number 50 180 capsules 30 Day Supply Of A Dietary Supplement Composition—The recommended daily dosage of six capsules provides as follows: Ingredients * * * % M. D. R.—Vitamin C (Ascorbic Ac.) 210.0 Milligrams 433% * * * Iodine (KI) 0.45 Milligrams 450% * * * Calcium (Bone Phosphate) 950.0 Milligrams 125% Phosphorus (Bone Phosphate) 565 Milligrams 75% The Purpose Of This Product Is Nutritional."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article, namely, "The recommended daily dosage of six capsules provides as follows: * * * Calcium * * * 950.0 Milligrams 125% M. D. R." and "* * * Phosphorus * * * 565 Milligrams 75% M. D. R.," were false and misleading since 6 capsules of the article provided less than 950 milligrams of calcium and less than 125 percent of the minimum daily requirement for calcium, and less than 565 milligrams of phosphorus and less than 75 percent of the minimum daily requirement for phosphorus; and the following statements in the labeling of the article, namely, "The recommended daily dosage of six capsules provides as follows: * * * Vitamin C (Ascorbic Acid) 210.0 Milligrams 433% M. D. R." and "Raymor No. 50 * * * A multivitamin * * * dietary supplement containing * * * 210.0 mgs. C * * * in the recommended daily dosage of six capsules," were false and misleading since 6 capsules of the article provided less than 210 milligrams of vitamin C (ascorbic acid) and less than 433 percent of the minimum daily requirement for vitamin C.

Further misbranding, Section 502 (a), the labeling of the article consisting of the issues of the "Raymor Nutritional Review," mentioned above, was also false and misleading. Such labeling when taken as a whole, as well as in the specific statements and read in the light of the setting in which such labeling was intended to be read, conveyed to the public a meaning which represented and suggested that the article was effective for successful growth, and maintenance of health; that it was effective, by reason of its content of choline and inositol, for arteriosclerosis; by reason of its content of vitamin B_{12}, for chronic dermatitis and chronic urticaria; by reason of its content of vitamin E, in the management of retrolental fibroplasia; for neurologic disturbances in diabetic sufferers; for psychogenic asthma; to prevent intravascular coagulation and nutritional breakdown; to improve metabolism and cellular processes by replenishing all known deficiencies; to prevent and treat common chronic diseases—hypertension, diabetes, cancer, arthritis, degenera-

tive diseases of the liver and kidneys, obesity, and cardiovascular-renal disease; arteriosclerosis, pain in rheumatoid arthritis, increased tendency for accidents caused by obesity, chronic physical and mental ill health, and congenital debility in infants; to accelerate wound healing and lessen the possibility of intercurrent infection; for "psychomatic" disorders of the heart, including irregularities of rhythm, unusual sensations about the heart such as oppression, tightening, pain, numbness, shortness of breath, feeling of faintness, weakness, and "all gone," free perspiration and sinking sensation; to improve vision in senile muscular degeneration; by reason of its content of liver and vitamin B complex, to remedy diarrhea following use of antibiotics; by reason of its content of vitamins, minerals, and amino acids, to remedy lesions of the mouth; by reason of its content of liver, to remedy reproductive failure; to remedy nervous illness in elderly people; to prevent invalidism and senility in the aging, breaking down of older individuals and emotional stress and psychological changes in the aged, manifesting themselves in nervousness, depression, insomnia, and "a wide variety of somatic symptoms, difficulties in memory, irritability, insomnia, and a general feeling of apprehensiveness and restlessness"; to relieve elderly people from the stresses and strains of life produced through functional disturbances of nervous origin and anxiety as to organic illnesses; to exert a favorable influence upon the entire outlook of the consumer; to prolong the period of the consumer's activity; by reason of its content of folic acid, for diarrhea and colitis; by reason of its vitamin B_{12} content, for spastic paraplegia, spinocerebral syndromes of the acromegaly type, cerebellar atrophy, and Korsakoff's psychosis and early cases of polyneuritis when not associated with rheumatic disorders. The article was not effective for such purposes, and it was not capable of fulfilling the promises of benefit stated and implied. The *Raymor No. 50 capsules* were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

The article, together with certain other articles, was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 25, 1953. Default decree of condemnation and destruction.

4135. Misbranding of Private Formula tablets, Kimball tablets, and Kao-Kim tablets. U. S. v. 4 Drums, etc. (F. D. C. No. 34120. Sample No. 54445–L.)

LIBEL FILED: November 13, 1952, Eastern District of Wisconsin; amended libel filed January 9, 1953.

ALLEGED SHIPMENT: On or about August 28 and September 9, 1952, from Chicago, Ill.

PRODUCT: 4 drums of *Private Formula tablets*, 88 100-tablet bottles of *Kimball tablets*, and 93 100-tablet bottles of *Kao-Kim tablets* at Milwaukee, Wis., in the possession of the Health Products Co., together with a number of cartons and bottle labels for the *Kimball tablets* and the *Kao-Kim tablets*, a number of circulars entitled "A Few Points to be Remembered" and "Read What Eminent Physicians Say," and 4 window signs containing statements relating to the efficacy of the tablets and a sign about 4 feet by 12 feet over the entrance to the consignee's premises bearing the words "Why Suffer With Stomach Trouble? Money Back Guarantee."

RESULTS OF INVESTIGATION: The drums containing the *Private Formula tablets* were shipped in interstate commerce as described above, and upon their receipt

by the Health Products Co., at Milwaukee, Wis., a number of tablets in the drums were removed and repacked into bottles bearing labels designating the tablets as *Kimball tablets* or *Kao-Kim tablets*. The above-mentioned circulars, bottle labels, cartons, window signs, and the store front sign were prepared locally for the consignee.

LABEL, IN PART: (Drums) "Private Formula No. P–25,794 Date 9/9/52 Prepared for Health Products Co. * * * Active Ingredients: Bismuth Subnitrate 1 gr., Sodium Bicarbonate 10 gr., Magnesium Carbonate 7 gr., Pepsin NF 1–3000—1/10 gr., and Excipients"; and "Private Formula No. P–25,597 Date 8/27/52 Prepared for Health Products Co. * * * Active Ingredients: Bismuth Subnitrate 1 gr., Sodium Bicarbonate 10 gr., Magnesium Carbonate 7 gr., Oleoresin Ginger 1/75 gr., Malt Diastase 1 gr., Papain 1 gr., Pancreatin ½ gr., Pepsin NF 1–3000—1/10 gr., and Excipients."

(Bottles) "Kimball's Rays of Health * * * Kimball Tablets" and "Kao-Kim Rays of Health Kao-Kim Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the tablets, namely, the bottle and carton labels, the circulars, and the window signs and store front sign accompanying the article, were false and misleading. The statements represented and suggested that the tablets would restore and maintain health and that they were an adequate and effective treatment for gastritis, indigestion, bloating, nervousness, headaches, ulcers, stomach trouble, inflamed membranes of the stomach, and loss of weight and strength. The tablets would not restore and maintain health, and they were not an adequate and effective treatment for the diseases and conditions stated and implied.

Further misbranding, Section 502 (a), certain statements in the above-mentioned circulars which suggested and implied that the tablets consisted of "derivatives of minerals, vegetables and fruit" were misleading since none of the ingredients of the tablets was derived from sources ordinarily regarded as fruits and vegetables. The tablets were alleged to be misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1953. John J. McCloskey, Milwaukee, Wis., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the store front sign be released to the claimant on condition that the wording of the sign be changed to read "Why Suffer With Stomach Hyperacidity? Money Back Guarantee." The court ordered also that the tablets, together with their labeling other than the store front sign, be destroyed.

4136. Misbranding of Vit-Ra-Tox No. 21. U. S. v. 25 Cartons, etc. (F. D. C. No. 34391. Sample Nos. 62612–L, 62613–L.)

LIBEL FILED: January 6, 1953, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about December 16 and 24, 1952, V. E. Irons, Inc., from Franklin and Boston, Mass.

PRODUCT: 25 cartons of *Vit-Ra-Tox No. 21* at St. Louis, Mo., together with a number of leaflets entitled "No. 21 A Natural Food" and "What Price Refinement" and 1 copy of a newsletter dated October 24, 1952.

LABEL, IN PART: "V. E. Vit-Ra-Tox Irons Inc. No. 21A . . . Part of No. 21 A Natural Food with Green*life* Raw Veal Bone and Defatted Wheat Germ Vit-Ra-Tox No. 21A with Green*life* Green Life is a concentrate of the juices of 2 or more young, tender green cereal (grain) shoots (oats, corn, barley,

rye or wheat) ; raised in one of the richest soils known to man on the world's largest Organic Compost Farm near Kansas City, Mo.; extracted in a manner as to retain Nature's vitamins, living enzymes, synergists, and activating minerals (except Vitamin D) ; rich natural source of Carotene (provitamin A) and the complete natural complexes of Vitamins B, C, E, F, and K with the P fractions of the C complex and the Wulzen factor of the F complex, plus the living enzymes, synergists and mineral activators. It contains organic iron, calcium, phosphorus, iodine and a host of other minerals in trace amounts with *Live* Chlorophyll in its natural, *untreated*, and *edible* state. Also contains * * * Raw Veal Bone Meal with its natural marrow. (1 oz.) An excellent source of calcium, phosphorus, and amino acids in easily assimilable form" and "No. 21B V. E. Vit-Ra-Tox Irons Inc. A Natural Food This part containing: Garlic Derivative * * * Vit-Ra-Tox No. 21B Two green capsules contain the following: Garlic Derivative 4 Mgs. Formulated in the following Organic Base (good natural sources of nutritional elements) Wheat Germ Oil 129.6 Mgs. and Lecithin from soy beans 666.4 Mgs. are used as emulsifiers."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the accompanying leaflets and newsletter, when taken as a whole as well as through specific claims and in the setting in which they were presented, contained statements which represented and suggested that the average American diet is deficient in vitamins, minerals, and enzymes; that, as a result of such deficiencies, everyone is suffering from imperfect health and disease; that such conditions can only be eliminated by the ingestion of the article; that the article would be effective in the treatment, prevention, and cure of common infections, external and internal, and intestinal infections, ranging from amebic dysentery to paratyphoid; that the article was of special value for the circulatory system; that the article had a primary place in treating the symptoms of aging and would keep workingmen at high efficiency and guarded from illness; that the article was the solution to many of the most perplexing physical, special, and economic problems; that the article would prevent sterility and was of vital importance to prevent heart trouble; that the article would be effective in the treatment, prevention, and cure of heart trouble, diabetes, indigestion, anemia, nervousness, varicose veins, asthma, and hay fever, diseases of the digestive system, respiratory system, and the glands, bones, skin, and muscles, tuberculosis, cancer, pernicious anemia, marasmus, dentition difficulties and imperfect teeth in children and in adults, dyspepsias, diarrheas, constipation, obesity, inability to nurse children, neuroses, infantile paralysis, certain myalgias or "Rheumatism," dementia praecox, high blood pressure, low blood pressure, polio, arterial disease, flatulence, infections of the respiratory system, worms, lice, ulcers, and symptoms of aging; that the action of garlic in the article was comparable to that of penicillin and that garlic would make the dread symptoms of diphtheria present in the system disappear. Such representations and suggestions were false and misleading since the article was not effective in the treatment of the conditions stated and implied, and it was not capable of fulfilling the promises of benefit made for it. The article was alleged to be misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 30, 1953. Default decree of condemnation. The court ordered that a portion of the article be delivered to the Food and Drug Administration and that the remainder be destroyed.

4137. Misbranding of Lusalfa tonic. U. S. v. 20 Bottles * * *. (F. D. C. No. 35003. Sample No 55118–L.)

LIBEL FILED: April 21, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about March 30, 1953, by M. W. Henson, from Huntley, Ill.

PRODUCT: 20 8-ounce bottles of *Lusalfa tonic* at Milwaukee, Wis.

LABEL, IN PART: "Lusalfa Tonic Vitamins Enzymes Digestives—Prepared From Natural Young Alfalfa With Papain, Pepsin, Ox Gall, Hydrochloric Acid Added * * * Manufactured By Walton Laboratory Chicago, Illinois."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Recommended as Regulator for Nervousness, Sleeplessness, Lack of Appetite, Chronic Constipation, and General Debility" was false and misleading since the article would not be efficacious as a regulator for those conditions.

DISPOSITION: May 18, 1953. Default decree of condemnation and destruction.

4138. Misbranding of huckleberry leaves. U. S. v. 3 Bales, etc. (F. D. C. No. 34891. Sample No. 66865–L.)

LIBEL FILED: March 16, 1953, Middle District of Pennsylvania; libel amended April 1, 1953.

ALLEGED SHIPMENT: On or about October 22, 1952, from New York, N. Y.

PRODUCT: 3 225-pound bales of *huckleberry leaves* in bulk and 52 5-ounce labeled canisters and 750 unlabeled canisters of *huckleberry leaves* at Wilkes-Barre, Pa., in the possession of Temple Drugs, together with a number of loose labels reading in part, "Temp-L-Tea" and "Meta Tea." A circular entitled "Read what a friend says about Temp-L-Tea" was attached to each of the labeled canisters.

Analysis showed that the product consisted essentially of dried huckleberry leaves.

LABEL, IN PART: (Canister) "Temp-L-Tea (Vaccinium Myrtillus Dehydrated)."

RESULTS OF INVESTIGATION: The portion of the product contained in the canisters had been repackaged by the consignee from the bales in which such portion was contained when shipped in interstate commerce. It was found that the consignee also repackaged the bulk *huckleberry leaves* into canisters labeled "Meta Tea."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the canister labels and in the above-mentioned circular were false and misleading. The statements represented and suggested that the article was an adequate and effective remedy for diabetes, whereas it was not an adequate and effective remedy for diabetes.

Further misbranding, Section 502 (e) (1), the canister labels failed to bear the common or usual name of the article since "Vaccinium Myrtillus Dehydrated" was not the common or usual name of dried huckleberry leaves.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 14, 1953. Default decree of condemnation and destruction.

4139. Misbranding of X-O-Kreme ointment. U. S. v. 131 Jars, etc. (F. D. C. No. 34932. Sample No. 2748–L.)

LIBEL FILED: April 6, 1953, Southern District of Florida.

ALLEGED SHIPMENT: On or about October 6, 1952, by the Wright Pharmacal Co., from Birmingham, Ala.

PRODUCT: 131 1-ounce jars of *X-O-Kreme ointment* at Miami, Fla., together with a number of circulars entitled "New Wonder Drug Discovered."

LABEL, IN PART: (Jar) "X-O Kreme Ointment Contains: 1% Hexachlorophene, 1% Dichlorophene, Zinc Oxide and Lanolin in White Petroleum base."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned circular were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for resistant skin infections, sores, facial blemishes, and burns, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: May 4, 1953. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE*

4140. Misbranding of liniment. U. S. v. 2 Dozen Bottles, etc. (F. D. C. No. 33585. Sample No 36208–L.)

LIBEL FILED: September 10, 1952, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about June 30, 1952, by the Dr. Reed Liniment Co., from Portland, Ind.

PRODUCT: 2 dozen 12-ounce bottles of *liniment* at Lexington, Ky., together with a number of booklets headed "Foreword." Examination showed that the article contained 2.2 percent of bichloride of mercury instead of 0.0267 percent as represented.

LABEL, IN PART: (Bottle) "Dr. J. W. Reed's Absorbent Liniment * * * Contents Bichloride of Mercury, .0267% by weight; Turpentine; Gum Camphor; Muriatic Acid; Coloring Matter; Logwood Chips or Fl. Ext. Baptisia; Ethyl (Denatured) Alcohol, 80% by volume."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the accompanying booklets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for bone spavin, thoroughpin, capped hock, shoe boils, wind or road puffs, bunches of all kinds, lameness from any cause, weak joints, sweeny, rheumatism, fistula, poll evil, synovial bursae, big knee, sprains, grease heel, quarter crack, corns, cockle ankle, sprung knees, lump jaw, nail wounds, and open joints. The article was not an adequate and effective treatment for those conditions.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear a statement of the quantity or proportion of bichloride of mercury contained therein since the label declaration of the quantity of bichloride of mercury contained in the article was inaccurate.

DISPOSITION: October 9, 1952. Default decree of condemnation and destruction.

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*See also No. 4128.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4132) Action for declaratory judgment dismissed. Contains opinion of the court.
[2] (4125) Prosecution contested.

[1] (4132) Action for declaratory judgment dismissed. Contains opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1934

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4141–4160

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *June 17, 1954.*

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*For presence of a habit-forming narcotic without warning statement, see Nos. 4141–4144; omission of, or unsatisfactory, ingredients statements, Nos. 4141–4143, 4145, 4146; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4141–4145; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4141–4143, 4145.

300099—54——1

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4141. Misbranding of Seconal Sodium capsules, amphetamine hydrochloride tablets, dextro-amphetamine sulfate tablets, and pentobarbital sodium capsules. U. S. v. Charles J. Bridgman (Bridgman Drug), and Otto A. Greiser. Pleas of nolo contendere. Defendant Bridgman fined $900 and Defendant Greiser placed on probation for 6 months. (F. D. C. No. 33726. Sample Nos. 35050–L, 35054–L, 35414–L, 35415–L, 35422–L, 35423–L.)

INFORMATION FILED: May 4, 1953, Southern District of Iowa, against Charles J. Bridgman, trading as Bridgman Drug, Des Moines, Iowa, and against Otto A. Greiser, an employee of Mr. Bridgman.

ALLEGED VIOLATION: On or about November 19 and 26 and December 4 and 5, 1951, while a number of *Seconal Sodium capsules*, *amphetamine hydrochloride tablets*, *dextro-amphetamine sulfate tablets*, and *pentobarbital sodium capsules* were being held for sale at Bridgman Drug, after shipment in interstate commerce, the defendants caused various quantities of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* and *pentobarbital sodium capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and such repackaged drugs failed to bear labels containing the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the labels of the repackaged *amphetamine hydrochloride tablets* and *dextro-amphetamine sulfate tablets* failed to bear the common or usual name of each active ingredient of such drugs; and, Section 502 (f) (2), the labeling of the repackaged *amphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 4, 1953. The defendants having entered pleas of nolo contendere, the court fined Defendant Bridgman $900 and placed Defendant Greiser on probation for 6 months.

4142. Misbranding of methyltestosterone tablets, phenobarbital tablets, and amphetamine sulfate tablets. U. S. v. Goldberg Drug Store, Edward J. Rubas, and John Tarczewski. Pleas of guilty. Fine of $500 against store and fine of $250 against each individual, plus costs. (F. D. C. No. 33843. Sample Nos. 9448–L, 33531–L, 33537–L to 33539–L, incl., 33543–L to 33545–L, incl.)

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*See also No. 4157 (veterinary preparation).

INFORMATION FILED: February 18, 1953, Northern District of Illinois, against Goldberg Drug Store, a partnership, Chicago, Ill., and against Edward J. Rubas, an employee, and John Tarczewski, a pharmacist for the store.

ALLEGED VIOLATION: On or about October 6, 12, and 27, 1951, while quantities of *methyltestosterone tablets*, *phenobarbital tablets*, and *amphetamine sulfate tablets* were being held for sale at the Goldberg Drug Store, after shipment in interstate commerce, various quantities of such drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded; and, on or about October 3 and 12, 1951, while a number of *methyltestosterone tablets* were being held for sale at the Goldberg Drug Store, after shipment in interstate commerce, 3 bottles of such tablets were dispensed in the original bottles in which the tablets had been shipped in interstate commerce, without the prescription of a physician, which acts resulted in the tablets being misbranded. The partnership and Edward J. Rubas were charged with causing the acts of dispensing with respect to the *amphetamine sulfate tablets*, and the partnership and John Tarczewski were charged with causing the acts of dispensing with respect to the other drugs involved.

NATURE OF CHARGE: *Methyltestosterone tablets* (dispensed in original bottles). Misbranding, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use. (The bottles in which the tablets were shipped in interstate commerce did not bear adequate directions for use since they were exempt from such requirement by the label statement "Caution: To be dispensed only by or on the prescription of a physician." The act of dispensing the tablets without a physician's prescription, however, caused the exemption to expire.)

Phenobarbital tablets, *amphetamine sulfate tablets*, and *methyltestosterone tablets* (repackaged). Misbranding, Section 502 (b) (1) and (2), the drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use. Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (1), the *methyltestosterone tablets* and *amphetamine sulfate tablets* failed to bear labels containing the common or usual name of the drug.

DISPOSITION: June 12, 1953. The defendants having entered pleas of guilty, the court fined the partnership $500 and each individual $250, plus costs.

4143. Misbranding of dextro-amphetamine sulfate tablets, conjugated estrogens (equine) tablets, methyltestosterone linguets, and phenobarbital tablets. U. S. v. Black's Prescription Shop, Inc., Lorren R. Black, George E. Nicholas, and Virgil L. Haag. Pleas of nolo contendere. Corporation fined $60, plus costs, Defendant Black fined $60, and Defendants Nicholas and Haag each fined $30. (F. D. C. No. 34341. Sample Nos. 14792–L, 14793–L, 14795–L, 14796–L, 14798–L, 14800–L.)

INFORMATION FILED: April 28, 1953, Western District of Missouri, against Black's Prescription Shop, Inc., Kansas City, Mo., and Lorren R. Black, president of

the corporation, and George E. Nicholas and Virgil L. Haag, pharmacists for the corporation.

ALLEGED VIOLATION: On or about February 21, 26, 28, and 29, 1952, while a number of *dextro-amphetamine sulfate tablets, conjugated estrogens (equine) tablets. methyltestosterone linguets,* and *phenobarbital tablets* were being held for sale at Black's Prescription Shop, Inc., after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Black's Prescription Shop, Inc., and Lorren R. Black were charged with causing the acts of repacking and dispensing in each of the 6 counts of the information; George E. Nicholas was joined as a defendant in counts 1, 2, and 5; and Virgil L. Haag was joined as a defendant in counts 3, 4, and 6.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Misbranding, Section 502 (b) (1), the repackaged *methyltestosterone linguets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor. Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of such tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (2), the labels of the *dextro-amphetamine sulfate tablets, conjugated estrogens (equine) tablets,* and *methyltestosterone linguets* failed to bear the common or usual name of each active ingredient of the drugs.

DISPOSITION: May 22, 1953. The defendants having entered pleas of nolo contendere, the court fined the corporation $60, plus costs, Defendant Black $60, and Defendants George E. Nicholas and Virgil L. Haag $30 each.

4144. Misbranding of Dexedrine Sulfate tablets and Nembutal Sodium capsules. U. S. v. Guilford Drug Co., David Stang, William S. Stang, and James P. Norman. Pleas of not guilty. Tried to the court. Verdict of guilty. Fine of $1,500, plus costs, against company; imposition of sentence against individual defendants suspended and individuals placed on probation for 18 months. (F. D. C. No. 34809. Sample Nos. 978–L, 1585–L, 2100–L, 2101–L.)

INFORMATION FILED: March 31, 1953, Middle District of North Carolina, against the Guilford Drug Co., a partnership, Greensboro, N. C., and against William S. Stang and David Stang, partners in the partnership, and James P. Norman, a pharmacist for the partnership.

ALLEGED VIOLATION: On or about December 26, 1951, and February 26 and 29 and March 3, 1952, while a number of *Dexedrine Sulfate tablets* and *Nembutal Sodium capsules* were being held for sale at the Guilford Drug Co., after shipment in interstate commerce, various quantities of such drugs were repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

The Guilford Drug Co. was charged with causing the acts of repacking and dispensing in each of the 4 counts of the information, and William S. Stang

was joined as a defendant in count 1, David Stang in count 2, and James P. Norman in the remaining 2 counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Nembutal Sodium capsules* contained pentobarbital sodium, a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: A motion for dismissal of the information was filed by the defendants, but later it was denied. The case came on for trial before the court on July 15, 1953, upon the defendants' pleas of not guilty, and at the conclusion of the testimony, the court returned a verdict of guilty. The court fined the partnership $1,500, plus costs, suspended the imposition of sentence against the individual defendants, and placed the individual defendants on probation for 18 months.

4145. Misbranding of penicillin G potassium tablets and sulfadiazine tablets. U. S. v. Theodore M. Douglas and William H. Evans. Pleas of nolo contendere. Fine of $50 against Defendant Douglas and $100 against Defendant Evans, plus costs. (F. D. C. No. 33844. Sample Nos. 33535–L, 33550–L, 33562–L.)

INFORMATION FILED: February 18, 1953, Northern District of Illinois, against Theodore M. Douglas, a pharmacist, and William H. Evans, an employee of the Star Drug Store, at Chicago, Ill.

ALLEGED VIOLATION: On or about October 4 and 18, 1951, while a number of *penicillin G potassium tablets* were being held for sale at the Star Drug Store, after shipment in interstate commerce, each defendant caused a number of such tablets to be dispensed in the original containers in which the tablets had been shipped in interstate commerce, without the prescription of a physician, which acts resulted in the tablets being misbranded; and, on or about October 20, 1951, while a number of *sulfadiazine tablets* were being held for sale at the Star Drug Store, after shipment in interstate commerce, Defendant Evans caused a number of such tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: *Penicillin G potassium tablets.* Misbranding, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use. (The containers in which the tablets were shipped in interstate commerce bore no directions for use since they were exempt from such requirement by the label statement "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendants in dispensing the tablets without a physician's prescription, however, caused the exemption to expire.)

Sulfadiazine tablets. Misbranding, Section 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug;

and, Section 502 (f) (1) and (2), the repackaged tablets failed to bear labeling containing adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: June 12, 1953. The defendants having entered pleas of nolo contendere, the court imposed a fine of $50 against Defendant Douglas and $100 against Defendant Evans, plus costs.

4146. Misbranding of Glando tablets. U. S. v. 1 Bottle, etc. (F. D. C. No. 34904. Sample No. 57738–L.)

LIBEL FILED: March 20, 1953, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about December 31, 1952, and February 23, 1953, from Baltimore, Md.

PRODUCT: 1 bottle, containing 6,000 tablets, and 30 boxes, each box containing 16 tablets, of *Glando tablets* at Norfolk, Va., in the possession of the Medical Products Co., together with a number of loose labels.

RESULTS OF INVESTIGATION: The above-mentioned tablets had been shipped in interstate commerce in bulk containers, and after their receipt by the Medical Products Co., a number of the tablets were repackaged by that company into boxes labeled as indicated below.

LABEL, IN PART: (Box) "Glando Builds Up Vitality, Health And Strength Medical Products Company Norfolk, Va. Directions—One to two tablets after meals and bedtime * * * Recommended for loss of manhood, debility, lack of vitality, loss of appetite, weakness, etc."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the box labels of the tablets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for loss of manhood, debility, lack of vitality, loss of appetite, and weakness, and for building up health and strength. The article was not an adequate and effective treatment for such conditions and purposes.

Further misbranding, Section 502 (e) (2), the box label of the article failed to declare the presence and proportion of strychnine contained in the tablets and the presence of the active ingredients, cantharides and zinc phosphide; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since its labeling failed to bear warnings against use of this article, which contained strychnine, cantharides, and zinc phosphide.

The article was alleged to be misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 20, 1953. Default decree of condemnation and destruction.

4147. Misbranding of Niagara device. U. S. v. 13 Devices, etc. (F. D. C. No. 34938. Sample Nos. 20731–L, 48670–L.)

LIBEL FILED: April 8, 1953, Southern District of Iowa.

ALLEGED SHIPMENT: On or about January 9 and February 20, 1953, by Niamco, Inc., from Dallas, Tex.

PRODUCT: 13 *Niagara Hand Unit devices* and 7 all purpose *Niagara Portable devices* at Des Moines, Iowa, in the possession of the Niagara Massage Units Co., together with an accompanying placard entitled "Poor Circulation."

Examination showed that the devices were vibrators. The hand unit device was so designed as to adapt it to be held in the hand while being applied to any part of the body, and the all purpose device was designed for sitting or leaning upon or for resting the feet upon.

RESULTS OF INVESTIGATION: The above-mentioned placard was posted on the wall of the consignee's office, where the devices were demonstrated to potential purchasers. In addition, the devices were represented orally to be effective in treating the diseases and conditions hereinafter mentioned. Such representations were made by a saleslady for the consignee.

LABEL, IN PART: "Niagara of Adamsville, Pennsylvania Hand Unit [or "All Purpose Portable Model No. 5"]."

NATURE OF CHARGE: Misbranding, Section 502 (a), the placard accompanying the devices contained statements which represented and suggested that the devices were effective for circulatory disorders, which statements were false and misleading since the devices were not effective for circulatory disorders.

Further misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended, namely, for treating disorders of the heart, kidneys, circulation, gallbladder, colon, rectum, respiratory tract, joints, and nervous system; and for cancer, osteomyelitis, constipation, ulcers of the colon, multiple sclerosis, and asthma.

The devices were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 26, 1953. John L. Naughton, trading as the Niagara Massage Units Co., Des Moines, Iowa, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4148. Adulteration of chorionic gonadotropin. U. S. v. 944 Vials * * *. (F. D. C. No. 34945. Sample Nos. 38061–L, 38063–L.)

LIBEL FILED: April 13, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about August 29, 1952, by Ormonoterapia, s. r. l., from Milan, Italy.

PRODUCT: 944 vials of *chorionic gonadotropin* in boxes at New York, N. Y.

LABEL, IN PART: (Box) "Corionic Gonadotropin lyophilized in final containers box of 50 vials."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since the article was intended for injection into man and should be sterile, whereas it was contaminated with living micro-organisms.

DISPOSITION: May 6, 1953. Default decree of condemnation and destruction.

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*See also No. 4160 (veterinary preparation).

4149. Adulteration and misbranding of estrogens in oil. U. S. v. 15 Cartoned Vials * * *. (F. D. C. No. 34975. Sample No. 62366–L.)

LIBEL FILED: April 22, 1953, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about March 3, 1953, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: 15 cartoned vials of *estrogens in oil* at St. Louis, Mo. Examination showed that the article did not contain estrogens as they occur in, and are extracted from, the urine of pregnant mares in a proportion sufficient to render its potency equivalent, per cubic centimeter, to 20,000 International Units of estrone, nor to any number of International Units of estrone in excess of 15,200.

LABEL, IN PART: "10 cc. List #335 Estronat—20,000 In Corn Oil."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 20,000 International Units of estrone per cubic centimeter, due to estrogens from pregnant mares' urine.

Misbranding, Section 502 (a), the label statement "Estronat—20,000 * * * 20,000 International Units of Natural Estrogenic Hormone Substance * * * in each cc." was false and misleading as applied to the article, the potency of which, due to its content of estrogens as they occur in, and are extracted from, the urine of pregnant mares, was less than 20,000 International Units of estrone per cubic centimeter.

DISPOSITION: June 18, 1953. Default decree of condemnation and destruction.

4150. Adulteration and misbranding of Special tablets. U. S. v. 11,000 Tablets * * *. (F. D. C. No. 35212. Sample No. 62054–L.)

LIBEL FILED: May 1, 1953, Southern District of Illinois.

ALLEGED SHIPMENT: On or about August 9, 1952, from St. Louis, Mo., to Decatur, Ill., and from there transferred to Chillicothe, Ill.

PRODUCT: 11,000 *Special tablets* in jars at Chillicothe, Ill. Analysis showed that the product contained approximately 1/4000 grain of nitroglycerin per tablet.

RESULTS OF INVESTIGATION: The product was shipped in bulk from St. Louis, Mo., and upon its receipt at Decatur, Ill., was repackaged into jars by Sly & Co. The tablets were shipped by Sly & Co. to Dr. H. V. Thomas at Chillicothe, Ill.

LABEL, IN PART: (Jar) "Special Tablets * * * prepared for Dr. H. V. Thomas Each C. T. Contains: Sodium Nitrite ½ gr. Nitroglycerine 1/200 gr. Aconite 3/30 gr. Podophylline 1/40 gr. Sodium Bicarbonate 2 grs. * * * Distributed By Sly and Company * * * Decatur, Illinois."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 1/200 grain of nitroglycerin per tablet.

Misbranding, Section 502 (a), the following statement on the jar label "Each C. T. Contains: * * * Nitroglycerine 1/200 gr." was false and misleading as applied to the article, which contained less than 1/200 grain of nitroglycerin per tablet.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 16, 1953. Default decree of condemnation and destruction.

4151. Adulteration and misbranding of Natrico tablets. U. S. v. 140 Bottles * * *. (F. D. C. No. 35204. Sample No. 49893–L.)

LIBEL FILED: May 1, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about March 2, 1953, by Bonded Laboratories, Inc., from Brooklyn, N. Y.

PRODUCT: *Natrico tablets.* 140 bottles, each containing 1,000 tablets, at East Orange, N. J. Examination showed that the product contained more than the declared quantity of sodium nitrite, namely, 79.5 milligrams per tablet.

LABEL, IN PART: (Bottle) "Pulvoids No. 373 Natrico * * * E. C. Green Each enteric coated Pulvoid Contains: * * * Sodium Nitrite 60 mg. (1 gr.)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 60 milligrams (1 grain) of sodium nitrite per tablet.

Misbranding, Section 502 (a), the label statement "Each enteric coated Pulvoid Contains: * * * Sodium Nitrite 60 mg. (1 gr.)" was false and misleading as applied to a product which contained more than the declared quantity of sodium nitrite.

DISPOSITION: June 30, 1953. Default decree of condemnation and destruction.

4152. Adulteration and misbranding of Special Formula hard filled capsules. U. S. v. 1 Drum, etc. (F. D. C. No. 35035. Sample No. 54644–L.)

LIBEL FILED: May 13, 1953, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about October 25, 1949, from Cleveland, Ohio.

PRODUCT: 1 drum containing 20,400 capsules and 1 drum containing 24,900 capsules of *Special Formula hard filled capsules* at Ann Arbor, Mich. Analysis showed that the product contained 5 percent of the declared amount of aspirin.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 2 grains of aspirin per capsule.

Misbranding, Section 502 (a), the label statement "Each capsule contains: * * * Aspirin 2 grain" was false and misleading as applied to the article, which contained less than 2 grains of aspirin per capsule.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1953. Default decree of condemnation and destruction.

4153. Adulteration and misbranding of adhesive strips. U. S. v. 183 Boxes * * *. (F. D. C. 34948. Sample No. 59244–L.)

LIBEL FILED: April 10, 1953, Middle District of North Carolina.

ALLEGED SHIPMENT: On or about December 19, 1952, by the Handy Pad Supply Co., from Worcester, Mass.

PRODUCT: 183 boxes of *adhesive strips* at Lexington, N. C.

LABEL, IN PART: (Box) "100 Ideal Adhesive Strips 1" x 3¼" Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality fell below the official standard since the article was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading as applied to the article, which was not sterile but was contaminated with living micro-organisms.

DISPOSITION: June 29, 1953. Default decree of condemnation and destruction.

4154. Adulteration and misbranding of clinical thermometers. U. S. v. 8 Dozen * * *. (F. D. C. No. 34920. Sample No. 56892–L.)

LIBEL FILED: March 30, 1953, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 5, 1953, by the Cardinal Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 8 dozen *clinical thermometers* at Cleveland, Ohio. Examination of 24 thermometers showed that 1 was a hard shaker; that 1 failed to meet the test for retreating index; and that 2 failed to meet the test for accuracy.

LABEL, IN PART: "Cardinal Fever Thermometer Kind—Oral."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article did not comply with the stated specifications: (On 1 dozen package) "These thermometers have been manufactured according to the rules and regulations, and have been compared with the standard thermometers, verified By The United States Bureau of Standards," (on unit package) "This thermometer has been made according to regulations and compared with standard thermometers verified By The U. S. Bureau of Standards," and (on leaflet enclosed in each unit package) "* * * thermometer * * * has been * * * tested and found to meet all the requirements and tests specified in the United States Department of Commerce, Commercial Standard CS1–42 for Clinical Thermometers. This Certificate is supported by a record of test of this thermometer * * *."

DISPOSITION: April 28, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4155. Misbranding of bonemeal and bonemeal tablets. U. S. v. Stanley W. Danvers (Nu-Age Products, Nu-Age Products Co., and Nu-Age Biorganic Products). Plea of guilty. Fine of $750, plus costs. (F. D. C. No. 33735. Sample Nos. 29171–L, 30511–L, 34945–L.)

INFORMATION FILED: December 23, 1952, Western District of Pennsylvania, against Stanley W. Danvers, trading as Nu-Age Biorganic Products, Nu-Age Products, and Nu-Age Products Co., at Loupurex, Pa.

ALLEGED SHIPMENT: On or about July 26, November 30, and December 1, 1951, from the State of Pennsylvania into the States of Oregon, Washington, and Wisconsin.

LABEL, IN PART: "Bone Meal with Vitamins A–C–D Each Tablet Contains: Bone Phosphate (A Purified Bone Meal)—7½ Grains Vitamin A 2,000 U. S. P. Units Vitamin C (Ascorbic Acid) 15.0 Milligrams Vitamin D (Irradiated Ergosterol) 150 U. S. P. Units Distributed By Nu-Age Products Company 1926 W. Railroad Street Loupurex, Pa. Six Tablets Daily Contain The

*See also Nos. 4146, 4147, 4149–4154.

following Percent of The Minimum Daily Adult Requirement: Calcium 133% Phosphorous 60% Vitamin A 300% Vitamin C 300% Vitamin D 225%," and "Purified Bone Meal * * * Distributed by Nu-Age Products Co. 1926 W. Railroad Street Loupurex, Pa. Calcium 33% Phosphorous 15% Ratio Ca/P 2.17 3 grams (approximately one level teaspoonful) daily furnish: Calcium (Ca), 1 gram, approximately 1⅓ times the minimum daily requirements of a child or an adult and ⅔ that of a pregnant or lactating woman; Phosphorus (P), 450 milligrams, approximately ⅗ of the minimum daily requirements of a child or an adult and 3/10 that of a pregnant or lactating woman."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a pamphlet entitled "Bone Phosphate A Supplementary Source of Calcium and Phosphorous," accompanying the articles, were false and misleading. The statements represented and suggested that deficiencies of calcium and phosphorous are prevalent and are primary causes of tooth decay, irritability of the nervous system, tense feeling, jagged nerves, restlessness, sleeplessness, nervousness, tired feeling after shopping, etc., poor teeth, hemorrhages, nonhealing wounds, stunted growth, low blood pressure, angina pectoris, facial neuralgia, "migrane" headache, easy dislocation of the hip, swelling of the ankles, boils, psoriasis, faintness, weakness of the lower limbs, night sweats, hoarseness, dropsy, epilepsy, blue lips, blue skin, heart conditions, uterine pains, premature graying of the hair, and contracting of the esophagus; that deficiencies of fluorine and calcium are responsible for prolapsus of the organs, blood tumors, varicose veins, and weakening of ligaments and elastic tissues, permitting ankles to turn: and that calcium, phosphorus, and fluorine, as supplied by the articles, would prevent or remedy such conditions, make for longevity, enable the blood stream to provide normal body functioning, correct and prevent much ill health, protect against premature aging, protect the health of pregnant and nursing mothers, stimulate the reproductive organs of otherwise normal persons, eliminate danger of gangrene after operations, render firmer the walls of the arteries, and furnish the proper constituents to keep the human body in good nutrition. These statements were false and misleading in that deficiencies of calcium and phosphorus are not prevalent and, with or without fluorine, are not primary causes of, or responsible for, the disease conditions stated; and calcium, phosphorus, and fluorine, as contained in the articles, would not fulfill the promises of benefit stated and implied.

DISPOSITION: August 26, 1953. The defendant having entered a plea of guilty, the court fined him $750, plus costs.

4156. Misbranding of desiccated liver tablets. U. S. v. 5 Bottles, etc. (F. D. C. No. 35228. Sample No. 50203–L.)

LIBEL FILED: May 7, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about March 5, 1953, by Richards Laboratories, from New York, N. Y.

PRODUCT: 5 100-tablet bottles, 4 300-tablet bottles, and 3 500-tablet bottles of *desiccated liver tablets* at Newark, N. J., together with a number of pamphlets entitled "The dramatic story of Desiccated Liver A Wonderful New Protective Food." The label of the article stated that 12 tablets, the amount recommended to be taken each day, would supply 72 grains of desiccated liver, representing 4½ times as much fresh liver. On this basis, the recommended daily intake represented less than 1 ounce of fresh liver.

LABEL, IN PART: (Bottle) "6 gr. Tablets Desiccated Liver N. F. Whole liver, defatted and desiccated. As a natural source of the Vitamin B Complex * * * Directions: * * * 4 tablets, after each meal * * * Each part of the desiccated liver is derived from 4½ parts of whole, raw mammalian liver * * * Twelve tablets (containing 72 grains or 4.6 gms. desiccated liver)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets accompanying the article were false and misleading. The statements represented and suggested that the article, when taken as directed, would prevent fatigue, would be effective for anemia, would prevent cancer, and would effect retention of the original color of hair. The article, when taken as directed, would not prevent fatigue, would not be effective for anemia, would not prevent cancer, and would not effect retention of the original color of the hair.

DISPOSITION: June 30, 1953. Default decree of condemnation and destruction.

4157. **Misbranding of Tuttle's Family Elexer and Tuttle's Elexer. U. S. v. 43 Cartoned Bottles, etc.** (F. D. C. No. 34921. Sample Nos. 44946–L, 44947–L.)

LIBEL FILED: On or about April 6, 1953, District of Rhode Island.

ALLEGED SHIPMENT: On or about November 4, 1952, and January 13, 1953, by the Tuttle's Elixir Co., from Boston, Mass.

PRODUCT: 43 cartoned bottles of *Tuttle's Family Elexer* and 107 bottles of *Tuttle's Elexer* at Providence, R. I. A leaflet entitled "What You Should Know About Tuttle's Family Elexer" was enclosed in each carton of *Tuttle's Family Elexer*. A leaflet entitled "Important To All Horse Owners" was enclosed with each bottle of *Tuttle's Elexer*, in which leaflet there appeared an offer of a free copy of a booklet entitled "Veterinary Experience By S. A. Tuttle, V. S.," wherein representations were made regarding *Tuttle's Family Elexer* and *Tuttle's Elexer*.

LABEL, IN PART: (Carton and bottle) "Tuttle's Family Elexer * * * For External Use Only 30 Per Cent Alcohol Contents 4 Fluid Ounces Gives Relief From Pain Directions For Use * * * Fabricated from the Following Ingredients: Gum Camphor, U. S. P. Turpentine, Ox Gall, Oil of Wintergreen, Hartshorn, Oil of Hemlock, Distilled Water, Alcohol 30 per cent"; (bottle) "Tuttle's Elexer Special Veterinary Liniment * * * For External Use Only Contains 4½ Net Ounces Fabricated from the following ingredients:—Alcohol 30 per cent, Gum Camphor, U. S. P. Turpentine, Oil of Hemlock, Ox Gall, Ammonia Solution, Distilled Water."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases and conditions for which the articles were offered in the above-mentioned booklet, as follows: (*Tuttle's Family Elexer*) "For the cure of la grippe, pneumonia, rheumatism, all joint affections, cholera morbus, diarrhea; to afford relief from suffering and torture; to draw all inflammation to the surface; to restore a natural and healthy circulation; to cure sprains, bruises, lame back, stiff neck, sore throat, neuralgia, toothache, poisonous bites, corns, chilblains, bunions, frostbite, burns, caked breasts, cold, asthma, croup, and coughs; to assist in developing and hardening muscles and to prevent them from stiffening; and for warding off chills after exercise" and (*Tuttle's Elexer*) "For simple fractures, bone spavin; to draw all inflammation to the surface; to restore a healthy circulation; for splints, thoroughpin, acne,

atrophy, callus, fistula, grease heel, laminitis or founder, mud fever, old sores, poll evil, colic, diabetes, diarrhea, dropsy, dysentery, jaundice, loss of appetite, sore mouth, bronchitis, catarrh, cough, difficult breathing, epizootic, influenza, laryngitis, nasal gleet, pink eye, pleurisy, pneumonia, sore throat, strangles, lameness, shoulder lameness, speedy cut, hip-joint lameness, nail in the foot, diarrhea in cattle, caked or inflammation of the bag or udder, and inflammation of the lungs."

Further misbranding, Section 502 (a), the following statements in the labeling of *Tuttle's Family Elexer* were false and misleading since the article was not effective in the treatment of the conditions suggested and implied: (Carton and bottle label) "Tuttle's Family Elexer * * * Gives Relief From Pain * * * It is recommended, to give relief of * * * lameness, chest colds * * * sprains" and (Leaflet) "For Sprains * * * and Common Chest colds."

DISPOSITION: May 15, 1953. Default decree of condemnation and destruction.

4158. **Adulteration of Solar Aire room conditioner.** U. S. v. 12 Devices, etc. (F. D. C. No. 34929. Sample No. 58851–L.)

LIBEL FILED: April 10, 1953, Northern District of Indiana.

ALLEGED SHIPMENT: On or about February 9, 1953, by Sears, Roebuck & Co., from Chicago, Ill.

PRODUCT: 12 cartoned devices known as *Solar Aire room conditioner* at South Bend, Ind., together with a number of leaflets entitled "Solar-Aire Guardian of Your Health and Comfort" and 1 carton containing an instrument to be used with the device and a leaflet entitled "What Is This Thing Called Humidity?"

The device consisted of a tank which would hold three gallons of water and contained a fan which, when plugged into the house electric line, forced air from the room to pass through a moistened filter pad. A small pump was incorporated in the device to circulate water through the filter pad and thus keep it moist.

LABEL, IN PART: (Metal plate attached to device) "Model No. 7600 Solar Aire Room Conditioner Filters and Humidifies Solar-Sturges Mfg. Division Pressed Steel Car Company, Inc. Melrose Park, Ill."; (carton containing instrument for use with the device) "Taylor Humidiguide Ashton Model No. 5546."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the leaflet entitled "Solar-Aire Guardian of Your Health and Comfort" which was shipped with the device, was false and misleading. The labeling represented and suggested that the article provided an adequate and effective treatment for preventing sinus infections, throat infections, lung infections, loss of appetite, nervous tensions, respiratory infections, colds, and sore throat, and for treating hay faver, asthma, and skin itch. The article did not provide an adequate and effective treatment for such purposes and conditions.

DISPOSITION: June 8, 1953. The Pressed Steel Car Co., Inc., having appeared as claimant, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law. On June 25, 1953, an amended decree was entered providing for the removal of the above-mentioned leaflets under the supervision of the Food and Drug Administration. The leaflets were removed and destroyed.

4159. Misbranding of Miracle hearing aid. U. S. v. 450 Devices, etc. (F. D. C. No. 35209. Sample No. 39517–L.)

LIBEL FILED: May 6, 1953, Southern District of California.

ALLEGED SHIPMENT: On or about August 8, 1952, from East Orange, N. J., by Borden Conrad, trading as the Miracle Hearing Aid Co. of California.

PRODUCT: 450 devices called the *Miracle hearing aid* at Hollywood, Calif., together with a number of circulars entitled "Sensational, New Miracle Hearing Aid" and a number of leaflets entitled "Instructions and Guide in Using and Handling Miracle Hearing Aid Efficiently."

The device consisted of a piece of wire, twisted into the shape of a miniature tuning fork, and rubber discs with perforated centers into which the wire was to be inserted.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars and leaflets accompanying the device were false and misleading. The statements represented and suggested that the device provided an adequate and effective aid to auditory acuity of deaf persons, whereas the device did not provide an adequate and effective aid to the auditory acuity of deaf persons.

DISPOSITION: June 5, 1953. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE*

4160. Adulteration and misbranding of Hepto-Sol solution. U. S. v. 39 Bottles * * *. (F. D. C. No. 35010. Sample No. 38936–L.)

LIBEL FILED: On or about April 28, 1953, Western District of Virginia.

ALLEGED SHIPMENT: On or about March 19, 1953, by the Atlantic Supply Co., from Duncannon, Pa.

PRODUCT: 39 1-gallon bottles of *Hepto-Sol solution* at Harrisonburg, Va. Analysis showed that each 100 cc. of the product contained not more than 0.12 gram of 2-amino-5-nitrothiazole.

LABEL, IN PART: "1 Gallon Hepto-Sol Solution of 2-Amino-5-Nitrothiazole In An Excess of Sodium Hydroxide for the Prevention and Control of Enteroheptatitis (Blackhead) in Turkeys. Each 100 CC Contains 7.68 Grams of 2-Amino-5-Nitrothiazole."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 7.68 grams of 2-amino-5-nitrothiazole in each 100 cc.

Misbranding, Section 502 (a), the label statement "Each 100 CC Contains 7.68 Grams of 2-Amino-5-Nitrothiazole" was false and misleading as applied to the article, which contained less than 7.68 grams of 2-amino-5-nitrothiazole in each 100 cc.

DISPOSITION: June 5, 1953. Default decree of condemnation and destruction.

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*See also No. 4157.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4144) Prosecution contested.

[1] (4144) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1954

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4161–4180

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *July 12, 1954.*

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*For presence of a habit-forming narcotic without warning statement, see No. 4163; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4161, 4163; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4161, 4163; cosmetic, actionable under the drug provisions of the Act, No. 4175.

302839—54——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4161. Misbranding of dextro-amphetamine sulfate tablets, thyroid tablets, and pentobarbital sodium capsules. U. S. v. Myron B. Deepe (Gillmer Park Cut Rate Store). Plea of nolo contendere. Sentence of 1 year in jail on count 1 suspended and fine of $200, plus costs, on count 2; imposition of sentence on remaining 4 counts of information suspended and individual placed on probation for 2 years. (F. D. C. No. 34319. Sample Nos. 9667–L, 9668–L, 9673–L to 9676–L, incl.)

INFORMATION FILED: March 23, 1953, Northern District of Indiana, against Myron B. Deepe, trading as the Gillmer Park Cut Rate Store, at South Bend, Ind.

NATURE OF CHARGE: On or about April 11, 1952, while a number of *dextro-amphetamine sulfate tablets* and *thyroid tablets* were being held for sale at the Gillmer Park Cut Rate Store, after shipment in interstate commerce, the defendant caused a number of tablets of such drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (1) and (2), the repackaged drugs failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling of the repackaged *dextro-amphetamine sulfate tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

On or about May 5 and 8, 1952, while a number of *dextro-amphetamine sulfate tablets*, *thyroid tablets*, and *pentobarbital sodium capsules* were being held for sale at the Gillmer Park Cut Rate Store, after shipment in interstate commerce, the defendant caused certain quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer the drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded.

DISPOSITION: June 8, 1953. The defendant having entered a plea of nolo contendere, the court sentenced the defendant to 1 year in jail on count 1, suspended this sentence, and placed the defendant on probation for 2 years, and imposed a fine of $200, plus costs, on count 2. The court suspended the imposition of sentence on the remaining 4 counts of the information and placed the defendant on probation for 2 years, which period was to run concurrently with the probation imposed on count 1.

4162. Misbranding of dextro-amphetamine sulfate tablets and capsules containing a mixture of Seconal Sodium and Amytal Sodium. U. S. v. Samuel Ross (Baldwin Harbor Pharmacy). Plea of guilty. Defendant fined $100 and placed on probation for 1 year. (F. D. C. No. 35103. Sample Nos. 37242–L, 37394–L.)

INFORMATION FILED: June 24, 1953, Eastern District of New York, against Samuel Ross, trading as the Baldwin Harbor Pharmacy, Baldwin, Long Island, N. Y.

NATURE OF CHARGE: On October 17 and November 14, 1952, while a number of *dextro-amphetamine sulfate tablets* and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were being held for sale at the Baldwin Harbor Pharmacy, after shipment in interstate commerce, the defendant caused a number of the capsules and tablets to be dispensed upon requests for refills of written prescriptions without obtaining authorization by the prescribers. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded.

DISPOSITION: July 23, 1953. The defendant having entered a plea of guilty, the court fined him $100 and placed him on probation for 1 year.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4163. Misbranding of Seconal Sodium capsules. U. S. v. J. George Moore (Moore's Pharmacy), and Edgar H. Holiman. Plea of nolo contendere by Defendant Holiman and plea of not guilty by Defendant Moore. Defendant Holiman fined $400 and placed on probation for 4 years. Case against Defendant Moore tried to a jury; verdict of guilty. Defendant Moore fined $1,000 and placed on probation for 4 years. (F. D. C. No. 34808. Sample Nos. 26884–L, 26885–L, 26887–L.)

INFORMATION FILED: June 26, 1953, Northern District of California, against J. George Moore, trading as Moore's Pharmacy, El Cerrito, Calif., and Edgar H. Holiman, an employee of the pharmacy.

ALLEGED VIOLATION: On or about August 30 and September 15 and 18, 1951, while a number of *Seconal Sodium capsules* were being held for sale at Moore's Pharmacy, after shipment in interstate commerce, the defendants caused various quantities of the capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged capsules failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged capsules contained Seconal Sodium, a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith a statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use.

DISPOSITION: Defendant Holiman entered a plea of nolo contendere, and Defendant Moore entered a plea of not guilty. The case against Defendant Moore came on for trial before the court and jury on September 8, 1953, and at the conclusion of the trial, the jury returned a verdict of guilty. On September 23, 1953, the court fined Defendant Moore $1,000 and placed him on probation for 4 years. On the same date, the court fined Defendant Holiman $400 and placed him on probation for 4 years.

*See also No. 4161.

4164. Misbranding of Taboyster tablets. U. S. v. 21 Bottles * * *. (F. D. C. No. 35290. Sample No. 57067–L.)

LIBEL FILED: June 4, 1953, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 17 and 19, 1953, by the Hollister Pharmacal Co., from Chicago, Ill.

PRODUCT: 21 bottles of *Taboyster tablets* at Toledo, Ohio.

LABEL, IN PART: (Bottle) "Hollister's Taboyster Tablets Contents 48 Tablets * * * Ingredients Tricalcium Phosphate Sodium Chloride Potassium Chloride Magnesium Phosphate Ferrous Sulfate Manganese Glycerophosphate Potassium Iodide Cupric Sulfate Crystalline Vit. A Acetate (Vitamin A) Thiamin HCL (Vitamin B–1) Riboflavin (Vitamin B–2) (G) Ascorbic Acid (Vitamin C) In especially prepared base containing vegetable protein and vegetable oil."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in rejuvenating strength and restoring sexual vigor, which were the conditions for which the article was offered in advertising sponsored by the distributor, the Hollister Pharmacal Co.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: August 6, 1953. Default decree of condemnation and destruction.

4165. Misbranding of vaginal diaphragms. U. S. v. 21 Diaphragms * * *. (F. D. C. No. 35260. Sample No. 54779–L.)

LIBEL FILED: May 20, 1953, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about March 23, 1953, by the Diaphragm & Chemical Co., from Chicago, Ill.

PRODUCT: 21 *vaginal diaphragms* in individual plastic boxes at Detroit, Mich.

LABEL, IN PART: (Box) "Molded D & C Narrow Rim"; (molded in diaphragm) "Molded D & C Long Life"; (glassine insert) "This Is The New Safety Seal D & C Diaphragm * * * Sold Only Through Accredited Surgical Supply Dealers."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: July 17, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4166. Adulteration and misbranding of liver injection. U. S. v. 500 Vials * * *. (F. D. C. No. 35210. Sample No. 26462–L.)

LIBEL FILED: On or about May 4, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about February 26, 1953, from Baltimore, Md.

PRODUCT: 500 vials of *liver injection* at Camden, N. J. Analysis showed that the vitamin B_{12} activity of the product was equivalent to 0.5 microgram of cyanocobalamin per cubic centimeter.

LABEL, IN PART: (Vial) "Multiple Dose Vial 30 cc. Liver Injection, Crude, U. S. P. Each cc. has a Vitamin B_{12} activity equivalent to 2 micrograms of cyanocobalamin."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Liver Injection Crude," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since each cubic centimeter of the article possessed a vitamin B_{12} activity equivalent to less than 2 micrograms of cyanocobalamin.

Misbranding, Section 502 (a), the label statements "Liver Injection, Crude, U. S. P. Each cc. has a Vitamin B_{12} activity equivalent to 2 micrograms of cyanocobalamin" were false and misleading as applied to the article, which did not conform to the specifications of the United States Pharmacopeia for liver injection crude and the vitamin B_{12} activity of which was equivalent to less than 2 micrograms of cyanocobalamin per cubic centimeter.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: July 1, 1953. Default decree of condemnation and destruction.

4167. Adulteration and misbranding of AAC Compound tablets and Compressed tablets. U. S. v. 22 Bottles, etc. (F. D. C. No. 34981. Sample Nos. 62045–L, 62047–L.)

LIBEL FILED: April 24, 1953, Southern District of Illinois.

ALLEGED SHIPMENT: On or about September 2, 1952, by Dumas-Wilson & Co., from St. Louis, Mo.

PRODUCT: 22 1,000-tablet bottles and 6 3,000-tablet bottles of *AAC Compound tablets* and 4 5,000-tablet bottles and 3 1,000-tablet bottles of *Compressed tablets* at Decatur, Ill.

Analysis showed that each *AAC Compound tablet* contained approximately 1.4 grains of acetophenetidin and that each *Compressed tablet* contained approximately 1/11 grain of kermes mineral (antimony sulfide, golden).

RESULTS OF INVESTIGATION: The drugs involved, when shipped in interstate commerce, were packaged in bulk containers, and upon their receipt by the consignee, were repacked into bottles and relabeled by the consignee.

LABEL, IN PART: *AAC Compound tablets.* (Bottle) "Acetophenetidin 2½ grs. (Derivative of Acetanilid) Acetylsalicylic Acid 3½ grs. Caffeine Alkaloid ½ gr. * * * Distributed by Sly and Company * * * Decatur, Illinois"; (bulk container) "Contains 50,850 Specifications Compressed Tablets Mottled Each tablet contains: Aspirin 3.5 grs. Acetophenetidin 2.5 grs. Caffeine Alk. 0.5 gr."

Compressed tablets. (Bottle) "Each tablet contains: Kermes Mineral 1/6 gr. Powdered Ipecac 1/12 gr. * * * Sly and Company * * * Decatur, Illinois"; (bulk container) "Contains 50,100 Specifications Compressed Tablets Each tablet contains: Kermes Mineral 1/6 gr. (Antimony Sulfide, Golden) Powdered Ipecac 1/12 gr."

NATURE OF CHARGE: *AAC Compound tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 2.5 grains of acetophenetidin per tablet. Misbranding, Section 502 (a), the label statements (bulk container) "Acetophenetidin 2.5 grs." and (relabeled bottle) "Acetophenetidin 2½ grs." were false and misleading as applied to a product which contained less than 2.5 grains of acetophenetidin per tablet.

Compressed tablets. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

namely, 1/6 grain kermes mineral (antimony sulfide, golden) per tablet. Misbranding, Section 502 (a), the label statements (bulk container) "Each tablet contains: Kermes Mineral 1/6 gr. (Antimony Sulfide, Golden)" and (relabeled bottle) "Each tablet contains: Kermes Mineral 1/6 gr." were false and misleading as applied to a product which contained less than 1/6 grain of kermes mineral (antimony sulfide, golden) per tablet.

The articles were adulterated and misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: May 27, 1953. Default decree of condemnation and destruction.

4168. Adulteration and misbranding of clinical thermometers. U. S. v. 100 Thermometers * * *. (F. D. C. No. 35268. Sample No. 47630–L.)

LIBEL FILED: May 21, 1953, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about March 20, 1953, by the Cardinal Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 100 *clinical thermometers* at New Orleans, La. Examination of 24 thermometers showed that 3 would not give accurate readings.

LABEL, IN PART: (Etched on thermometer) "Cardinal Oral"; (insert in 6-unit package) "Certificate of Examination Clinical Thermometer."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported to possess.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to thermometers which failed to comply with the tests and specifications mentioned: (Insert) "* * * This certifies that the enclosed thermometers have been tested at 98°, 102° and 106° F. and are correct within plus or minus 2/10 F. at any of these test points. This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1–32 Department of Commerce.)" and "The enclosed thermometers are guaranteed to be of absolute accuracy."

DISPOSITION: June 23, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4169. Misbranding of Alfamint tablets, alfalfa tablets, alfalfa leaves, Alfa-Mint leaves, alfalfa seed tea, and alfalfa seed. U. S. v. 204 Bottles, etc. (F. D. C. No. 35279. Sample Nos. 20577–L to 20582–L, incl.)

LIBEL FILED: May 28, 1953, District of Minnesota.

ALLEGED SHIPMENT: On or about January 13 and February 23, 25, and 26, 1953, from Huntington Park and Imperial, Calif.

PRODUCT: 204 200-tablet bottles of *Alfamint tablets*, 6 200-tablet bottles of *alfalfa tablets*, 278 4-ounce packages of *alfalfa leaves*, 75 pounds of *alfalfa leaves* in a bulk container, 235 4-ounce packages of *Alfa-Mint leaves*, 225 8-ounce packages and 302 16-ounce packages of *alfalfa seed tea*, and 60 pounds of *alfalfa seed* in a bulk container, at Minneapolis, Minn., in the possession of

*See also Nos. 4166–4168.

the Pavo Co., together with a number of booklets entitled "Medicinal Value of Natural Foods," a number of leaflets entitled "Arthritic Pain Pavo Alfalfa May Be Your Answer," and a number of placards headed "Arthritic Pains? Alfalfa May Be Your Answer."

RESULTS OF INVESTIGATION: The articles were shipped in bulk containers from California, and upon their receipt by the Pavo Co., were in whole or in part repackaged and relabeled by the consignee. In the case of the *Alfa-Mint leaves*, investigation indicated that the consignee mixed some peppermint leaves with alfalfa leaves, but that the article was essentially alfalfa leaves flavored with peppermint. As to the above-mentioned printed matter, investigation disclosed that one copy of the booklet was on display in a showcase in the consignee's retail store and that other copies of the booklet were stored in cabinets in the retail store and in the consignee's wholesale branch. The leaflets were placed prominently at various places in the retail store where they could be seen readily and picked up by customers. The placards were displayed prominently in a show window and within the retail store.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets, leaflets, and placards accompanying the articles were false and misleading. The statements represented and suggested that each of the articles was an adequate and effective treatment for arthritis, diabetes, tuberculosis, rheumatism, Bright's disease, toxemia, jaundice, neuralgia, insomnia, nervousness, syphilis, constipation, lumbago, hardening of the arteries, dropsy, prostatitis, anemia, skin eruptions, poor complexion, inflammation of the bladder, colds, fevers, and gonorrhea, and for building blood, providing sound teeth and bones, producing milk for nursing mothers, increasing assimilation, increasing appetite, and strengthening the digestive glands. None of the articles was an adequate and effective treatment for such diseases and conditions. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 22, 1953. L. J. Audette, a partner in the Pavo Co., having appeared as claimant and consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for relabeling in compliance with the law, under the supervision of the Department of Health, Education, and Welfare.

4170. Misbranding of Lusalfa tonic. U. S. v. 30 Bottles, etc. (F. D. C. No. 35295. Sample No. 78943-L.)

LIBEL FILED: June 4, 1953, Western District of Kentucky.

ALLEGED SHIPMENT: On or about April 24, 1953, by the Walton Laboratories, from Marengo, Ill.

PRODUCT: 30 8-ounce bottles of *Lusalfa tonic* at Louisville, Ky., together with a number of mimeographed leaflets headed "The Walton Laboratories Announce Lusalfa gets results in Diabetic Cases," "'Gastric Physiology & Pathology,'" "Hydrochloric Acid And Vitamin B Complex Deficiency In Skin Disease," and "Diabetes Case Histories."

RESULTS OF INVESTIGATION: The labels which were on the bottles of the product when shipped were removed by the consignee. The label on a sample taken from a previous shipment stated that the article was prepared from natural young alfalfa with added papain, pepsin, oxgall, and hydrochloric acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned mimeographed leaflets which accompanied the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for diabetes, gas, insomnia, indigestion, ulcers resulting from hard drinking of ardent spirits, dyspepsia, pericardial pain, stomach trouble, liver malfunctioning, lack of pancreatic secretion, convulsions, chronic arthritis especially of the knees, coronary thrombosis, and cholecystitis; that it would provide all the amino acids, minerals, and vitamins essential to growth and nutrition; that it would help the unhealthy duodenum to properly break down food elements so that nutrition would be improved; and that it would aid the absorption of vitamins A and B complex. The article was not an adequate and effective treatment for such diseases and conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: July 10, 1953. Default decree of condemnation and destruction.

4171. Misbranding of Lumax and Adroxal. U. S. v. 288 Bottles, etc. (F. D. C. No. 35286. Sample Nos. 39519–L, 39995–L.)

LIBEL FILED: July 20, 1953, Southern District of California.

ALLEGED SHIPMENT: On or about May 12 and 15 and July 1, 1952, by Nyal Co., Inc., from Detroit, Mich.

PRODUCT: 288 1-pint bottles of *Lumax* and 72 1-pint bottles of *Adroxal* at Glendale, Calif.

LABEL, IN PART: (Bottle) "Nyal * * * Lumax Brand Of Antacid Adsorbent Aluminum Hydroxide Gel in combination with Magnesium Trisilicate * * * Indicated for the temporary relief of gastric hyperacidity and the symptoms of Peptic Ulcer" and "Clinic Adroxal Brand Of Antacid Adsorbent Aluminum Hydroxide Gel in combination with Magnesium Trisilicate * * * Indicated for the temporary relief of gastric hyperacidity and the symptoms of Peptic Ulcer * * * Jamieson Pharmacal Company Pharmaceutical Chemists Detroit, Michigan, U. S. A."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle labels of the articles were false and misleading. The statements represented and suggested that the articles were an adequate and effective treatment for the symptoms of peptic ulcer, whereas the articles were not an adequate and effective treatment for such symptoms.

DISPOSITION: August 18, 1953. Default decree of condemnation and destruction.

4172. Misbranding of vitamin capsules. U. S. v. 35 Bottles, etc. (F. D. C. No. 35343. Sample No. 50295–L.)

LIBEL FILED: July 1, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about April 7, 1953, by the Park Drug Co., from New York, N. Y.

PRODUCT: 35 bottles of *vitamin capsules* at Newark, N. J., together with a number of leaflets which accompanied the product and which were entitled "Feel Weary Instead Of Wonderful? Feel Old Instead Of Young? The Sensational New *Red Vitamin—B_{12}*—May Be *Your* Fountain Of Youth."

LABEL, IN PART: (Bottle) "100 Capsules Zinn's Vitamin B Complex With Liver, Folic Acid, Inositol, Choline And Vitamin B_{12} with the Red Vitamin

A Special Dietary Supplement * * * Each Capsule Contains: Vitamin B_1 (Thiamin Chloride) ____ 3 mg. Vitamin B_2 (Riboflavin) ____ 2 mg. Vitamin B_6 (Pyridoxine Hydrochloride) ____ 0.1 mg. Vitamin B_{12} (Activity Equiv.) ____ 1 microgram As in Streptomyces Fermentation Extractives Calcium Pantothenate ____ 1 mg. Niacinamide ____ 10 mg. Choline Dihydrogen Citrate ____ 50 mg. Inositol ____ 20 mg. Folic Acid ____ 0.5 mg. And other factors of the B complex as found in Liver and Yeast with Excipients, enclosed in an artificially colored gelatin capsule."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was effective to overcome fatigue, to make the user feel young, and to build blood, and that it was effective in the treatment of anemia which responds to vitamin B_{12}. The article was not effective for such purposes.

DISPOSITION: August 17, 1953. Default decree of condemnation. The court ordered that the product be delivered to a charitable organization for its use and not for sale.

4173. Misbranding of B-Amino Complex tablets. U. S. v. 27 Cartoned Bottles * * *. (F. D. C. No. 34935. Sample No. 54112-L.)

LIBEL FILED: April 7, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: On or about September 18, 1952, by Universal Nutritions, from New York, N. Y., to Cleveland, Ohio, and from there transported, on or about November 23, 1952, to Chicago, Ill., by a representative of a Chicago firm.

PRODUCT: 27 cartoned bottles of *B-Amino Complex tablets* at Chicago, Ill. A leaflet headed "If Your Body Could Talk It Would Say" was enclosed in each carton of the article.

Analysis showed that 6 tablets of the article supplied not more than 4.8 milligrams of iron and not more than 11.2 milligrams of vitamin B_1.

LABEL, IN PART: (Bottle) "100 Tablets B-Amino BAC-Complex A brand of amino acids, coenzymes, vitamins and minerals Daily dose of 6 tablets contains: Vitamins Vitamin B_1 (Thiamine Hydrochloride) 18.0 mg. * * * DI and Tri-Valent Minerals Iron (Ferric Citro Pyrophosphate Soluble) 28.8 mg. * * * Unitone Corporation Distributor New York 13, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "6 tablets contains: * * * Vitamin B_1 * * * 18.0 mg. * * * Iron * * * 28.8 mg." was false and misleading as applied to the article, which contained less than 18.0 milligrams of vitamin B_1 and less than 28.8 milligrams of iron per 6 tablets. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (a), the labeling of the article, namely, the retail package labels and the above-mentioned leaflet, was false and misleading. The labeling represented and suggested that the article, when used as directed, would supply an important quantity of protein; that it was needed by the eyes, ears, lungs, liver, intestines, muscles, brain, heart, stomach, kidneys, and the entire body; that it would supply increased energy to the heart, lungs, muscles, liver, and other important organs; that it would supply missing enzymes necessary to carry on body functions, such as growth, reproduction, secretion, nerve condition, muscular contraction, etc.; that it would

supply vitamins, proteins, and minerals in the correct proportion to stimulate the body to work as nature intended; that it would endow the user with vibrant life, health, and energy; that it would enable the liver to convert more than normal amounts of carbohydrates into energy; that it would transfer fatigue to quick energy; that it would prevent and correct disfunction in the energy conversion chemistry of body functioning; that it would reactivate all enzyme systems necessary for healthy body functioning; that it would activate the body cells to function as nature intended; and that it would supply needs that are missing from the food one eats. The article, when used as directed, would provide but a small fraction of one's normal consumption of protein; it was not capable of fulfilling the promises of benefit stated and implied; and it did not contain needed elements that are not available in commonly available foods. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the following statements in the above-mentioned leaflet, namely, " 'Unbalanced B Vitamins May Be Dangerous' . . . says The Journal of the American Medical Association in an Editorial of September 1, 1945. They say further . . . 'Extensive scientific evidence has revealed that if B Vitamins are administered in other than balanced proportions, they may create Vitamin Deficiencies rather than cure them.' . . . still quoting the JAMA, the Editorial continues 'Many B–Complex preparations available to the physician and public today are definitely unbalanced . . . either too much thiamine or not enough riboflavin, niacin, or pyridoxine.' " were false and misleading since the quotations did not appear in an editorial in the September 1, 1945, issue of the Journal of the American Medical Association, and since the article did not contain B vitamins in balanced proportions. The article was misbranded in this respect when introduced into and while in interstate commerce.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: August 14, 1953. Default decree of condemnation and destruction.

4174. Misbranding of Blue Ridge Mountain Minerals. U. S. v. 285 Packages, etc. (F. D. C. No. 35230. Sample Nos. 47618–L, 47619–L.)

LIBEL FILED: May 12, 1953, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about January 22, 1953, from Rome, Ga.

PRODUCT: 285 5½-ounce packages of *Blue Ridge Mountain Minerals* and 39 pounds of a raw material in bulk at Hattiesburg, Miss., in the possession of the National Mineral Co.

RESULTS OF INVESTIGATION: The product in the above-mentioned packages was repackaged by the National Mineral Co. from 3 unlabeled 100-pound bags in which the product had been shipped in bulk in interstate commerce. The 39 pounds of the raw material in bulk was the portion of the bulk shipment which had not been repackaged.

Examination showed that the product was a black mineral substance consisting essentially of water and acid-insoluble compounds of iron and aluminum, with a small amount of water-soluble iron compounds.

LABEL, IN PART: (Package) "Genuine Blue Ridge Mountain Minerals * * * Most Wonderful Tonic and Body Builder Contains Neither Drugs Nor Narcotics * * * Contents 5½ Ounces * * * For Old Sores and Skin Infections

* * * Packed and Distributed By National Mineral Company 1203 Cedar St. Hattiesburg, Mississippi."

NATURE OF CHARGE: Misbranding. Section 502 (a), certain statements on the package label were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for old sores and skin infections and that it would insure proper development of the body. The article was not an adequate and effective treatment for such conditions, and it would not insure proper development of the body. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: August 29, 1953. Default decree of condemnation and destruction.

4175. Misbranding of Mentos medicated lanolin. U. S. v. 15 Cases, etc. (F. D. C. No. 35254. Sample No. 26463–L.)

LIBEL FILED: May 20, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about February 28, 1953, by Mentos Products Co., Inc., from Philadelphia, Pa.

PRODUCT: 15 cases, each containing 24 4-ounce jars, and 5 cases, each containing 12 16-ounce jars, of *Mentos medicated lanolin* at Hammonton, N. J., together with a number of circulars headed "Mentos Medicated Lanolin The Best Lanolin Cream Of All!"

Examination showed that the article was a mixture of 7.4 percent lanolin with other ingredients.

LABEL, IN PART: (Jar) "Mentos *Medicated* Lanolin * * * A lanolin compound proved highly beneficial for hair * * * Active Ingredients: Lanolin."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the jar label and in the above-mentioned circular accompanying the article, were false and misleading. The statements represented and suggested that the article was chiefly lanolin, whereas the article was not lanolin but a mixture of a small amount (7.4 percent) of lanolin with other ingredients.

DISPOSITION: July 1, 1953. Default decree of condemnation. The court ordered that the product be delivered to charitable institutions.

4176. Misbranding of Trojan Stey. U. S. v. 288 Tubes, etc. (F. D. C. No. 35237. Sample No. 51416–L.)

LIBEL FILED: May 20, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about March 17 and 20, 1953, from East Newark, N. J.

PRODUCT: 288 unlabeled ½-ounce tubes and 84 labeled 1-ounce tubes of *Trojan Stey* at New York, N. Y., in the possession of the North Pharmacal Co., together with a number of circulars entitled "The chances are 3 to 1 that You can use trojan stey," a number of leaflets headed "I thought I'd Seen Everything. . . ," a number of circular inserts entitled "Trojan Stey," and a number of loose labels.

RESULTS OF INVESTIGATION: The above-mentioned circulars, leaflets, circular inserts, and loose labels were found to have been printed locally for the consignee.

LABEL, IN PART: (Tube) "Contains: Tetracaine 1% in a specially prepared base. trojan stey For indications and directions see accompanying circular ½ oz. North Pharmacal Co. New York 8, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in the above-mentioned circulars, leaflets, and circular inserts, accompanying the article, were false and misleading. The statements represented and suggested that the article was a new "discovery"; that its use would insure sexual compatibility and happiness in marriage; that it would eliminate female frigidity; and that it would not diminish sensation. The article was not new; it could not be relied upon to accomplish the purposes for which it was recommended; and it would diminish sensation by reason of its local anesthetic action. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 24, 1953. The North Pharmacal Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the above-mentioned circulars, leaflets, and circular inserts be destroyed, and that the product be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4177. Misbranding of Rado pads. U. S. v. 22 Pads, etc. (F. D. C. No. 35288. Sample No. 69676–L.)

LIBEL FILED: May 29, 1953, District of Colorado.

ALLEGED SHIPMENT: On or about April 30, 1953, from Missoula, Mont., by the Rado Pad Co.

PRODUCT: 22 cellophane-wrapped pads measuring 15 by 15 inches and 10 cellophane-wrapped pads measuring 9 by 9 inches, designated as the *Rado Pad*, at Denver, Colo., together with 85 pamphlets entitled "Now! The Rado Pad Co."

Examination showed that the device was a cloth pad containing crushed ore and that it did not have a significant amount of radioactivity.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets accompanying the article were false and misleading since the statements represented and suggested that the article provided an adequate and effective treatment for arthritis, sinus conditions, rheumatism, and all muscular ailments, whereas the article did not provide an adequate and effective treatment for such conditions.

DISPOSITION: July 13, 1953. Default decree of condemnation. The court ordered that the devices and the pamphlets be turned over to the Food and Drug Administration.

4178. Misbranding of Master violet ray outfit. U. S. v. 14 Packages, etc. (F. D. C. No. 35294. Sample Nos. 50206–L, 50207–L.)

LIBEL FILED: June 8, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about October 10, 1951, and April 2, 1952, by Master Appliances, Inc., from Marion, Ind.

PRODUCT: 14 packages designated "Master Violet Ray Outfit No. 2B," each package containing an electrical device labeled in part, "Master Appliances Inc * * * UL Marion, Indiana" and 3 glass tubes designated "No. 1 General Electrode," "No. 3 Comb-Rake Electrode," and "No. 12a Glass Electrode," and 9 packages designated "Master Violet Ray Outfit No. 9," each package containing an electrical device labeled, in part, "Master Appliances Inc * * * UL Marion, Indiana" and one glass tube designated "No. 1 General Electrode," at New York, N. Y. Each package when shipped contained also a circular entitled "The Master High Frequency (Violet Ray)." In addition, a number

of leaflets entitled "Master Appliances For Health and Beauty," which had been shipped by the printer from Chicago, Ill., were in the possession of the consignee. The article (both models) when plugged into an electric outlet, would provide a high frequency, high voltage electric discharge through partially evacuated glass tubes of various shapes. When held against the body, the glass tube would conduct the high voltage, high frequency electrical discharge to the skin.

NATURE OF CHARGE: Misbranding. Section 502 (a), certain statements in the above-mentioned leaflet entitled "Master Appliances For Health and Beauty," which accompanied the article, were false and misleading. The statements represented and suggested that the article would provide an adequate and effective treatment for achieving good health; for relieving all pain and congestion; for stimulating the circulation; for restoring vigor and youth; for facial blemishes; for baldness; for preventing baldness; and for innumerable disorders; and that it would insure a clear, healthy complexion. The article would not provide an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it. The article was misbranded in the above respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: July 9, 1953. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

4179. Misbranding of Ironated Hog Liquid and Black Hawk's Special Dairy Products. U. S. v. Black Hawk Chemical Co., Inc., and Howard J. Murphy. Pleas of guilty. Fine of $500, plus costs, against corporation and $20 against individual (F. D. C. No. 33777. Sample Nos. 48554–L, 48555–L.)

INFORMATION FILED: September 17, 1953, Northern District of Iowa, against Black Hawk Chemical Co., Inc., Cedar Falls, Iowa, and Howard J. Murphy, president and secretary of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of May 1, 1951, and February 8, 1952, from the State of Iowa into the State of Nebraska.

LABEL, IN PART: "Ironated Hog Liquid * * * Ingredients: Sodium Sulphate (Glauber salts), Manganese Sulphate (Epsom salts), Ammonium Hydroxide, Copper Sulphate, Potassium Permanganate, Tinc. Capsicum, Also contains water; Oil of Anise, Oil of Sassafras (Imitation)" and "Black Hawk's Special Dairy Products Pulv. Limestone, Bone Meal (steamed), Bone Black (spent), Yeast Culture (Baker Type), Sulphur, Glauber Salt (Sodium Sulphate), Salt, Charcoal (Hardwood), Bicarb. of Soda, Foenugreek, Licorice, Yeast (Brewers), Cobalt Carb., Soft Phosphate with Colloidal Clay, Copperas (Iron Sulphate), Ginger, Liquid Anise, Molasses Irradiated Yeast (Source of Vit. B_2), Soybean Oil Meal, Potassium of Iodide, Manganese Sulphate."

NATURE OF CHARGE: *Ironated Hog Liquid.* Misbranding, Section 502 (a), certain statements on the label of the article and on accompanying order blanks were false and misleading. The statements represented and suggested that the article would furnish a significant amount of iron; that it contained potassium permanganate; that it would be effective for controlling ordinary types of scours in hogs; that it would be effective for a rundown condition in sows and for slow growing unthrifty pigs; and that it would be an effective remedy for "necro." The article would not furnish a significant amount of iron; it did not contain potassium permanganate; it would not be effective for controlling

the ordinary types of scours in hogs; it would not be effective for a rundown condition in sows and for slow growing unthrifty pigs; and it would not be an effective remedy for "necro."

Black-Hawk's Special Dairy Products. Misbranding, Section 502 (a), certain statements contained in accompanying circulars entitled "Maximum Gain By Feeding Black Hawk Special Mineral Feeds" were false and misleading. The statements represented and suggested that the article would be an effective treatment and preventive for shy breeding, anemia, and lump jaw. The article would not be an effective treatment and preventive for such conditions.

DISPOSITION: September 17, 1953. Pleas of guilty having been entered, the court fined the corporation $500, plus costs, and the individual $20.

4180. Misbranding of calf medicine, cow capsules, and Laxotone. U. S. v. 239 Packages, etc. (F. D. C. No. 35205. Sample Nos. 41045–L to 41047–L, incl.)

LIBEL FILED: May 4, 1953, Eastern District of Washington.

ALLEGED SHIPMENT: On or about November 12 and December 10, 1952, by Dr. David Roberts Veterinary Co., from Waukesha, Wis.

PRODUCT: 170 4-ounce packages and 69 10-ounce packages of *calf medicine*, 18 packages of *cow capsules*, and 60 3½-ounce packages and 22 10-ounce packages of *Laxotone* at Spokane, Wash., together with a number of booklets entitled "The Practical Home Veterinarian by Dr. David Roberts, D. V. S." and "The New Cattle Specialist" and a number of leaflets entitled "Take Good Care of Your Livestock and Your Livestock Will Take Care of You."

LABEL, IN PART: (Package) "Calf Medicine For Loose Bowels * * * Ingredients: Sulfathiazole, Salol, Bismuth Subnitrate, Ginger Root, Tannic Acid, Nicotine, White Oak Bark, Anise, Chalk, Sulphocarbolates of Calcium, Sodium, Zinc, Yeast Meal," "Dr. David Roberts' Cow Capsule Ant-Acid Ingredients: Wheat Germ Oil, Brewers Yeast, Bicarbonate of Soda, Sugar," and "Dr. David Roberts Laxotone Ingredients: Nux Vomica (Strychnine 2.515 grs. in each ounce), Anise, Cascarin, Licorice, Poke Root, Burdock Root, Fennel, Ginger, Jalap, Aloes, Sugar, Senna."

NATURE OF CHARGE: *Calf medicine.* Misbranding, Section 502 (a), certain statements in the labeling, namely, the package label and the above-mentioned booklets and leaflets accompanying the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for diarrhea in cattle, horses, and swine; for calf scours, loose bowels of all livestock, and bowel disorders; and for scours in lambs when administered to the ewes. The article was not an adequate and effective treatment for such conditions and purposes. Further misbranding, Section 502 (a), the label statement "Ingredients: Sulfathiazole, Salol, Bismuth Subnitrate" was misleading in that the statement represented and suggested that sulfathiazole, salol, and bismuth subnitrate were present in the article in such proportions as to be of therapeutic significance when administered as directed, whereas such was not the case. (Analysis showed that the article contained, per tablespoonful, approximately 32 milligrams of sulfathiazole, 80 milligrams of salol, and 98 milligrams of bismuth subnitrate.)

Cow capsules. Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the package label and the above-mentioned bookets accompanying the article, were false and misleading. The statements represented and suggested that the article was of value in connection with

the breeding of cows and that it was an adequate and effective treatment for slow breeding in cows and failure to conceive. The article was not of value in connection with the breeding of cows, and it was not an adequate and effective treatment for the purposes represented.

Laxotone. Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the above-mentioned booklets and leaflets accompanying the article, were false and misleading. The statements represented and suggested that the article would keep the bowels in a normal condition, overcome the congestion associated with choking, keep the bowels regular, move the bowels naturally, and would act as a general stimulant, and that the article was an adequate and effective treatment for grass staggers, paralysis of the hind parts, red water in cattle, suppression of milk, fever, rheumatism in swine, sick cows, many disorders especially of cattle, bowel stoppage, bowel inaction and paralysis, azoturia, colic, impaction of bowels, bloating, diarrhea, and mastitis. The article was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: July 31, 1953. Default decree of condemnation. The court ordered that the actual physical destruction of the products should be postponed for a period of 30 days to give the shipper an opportunity to submit proper labels for the products. The products and their labeling were destroyed on September 2, 1953.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1](4163) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1934

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4181–4200

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *July 19, 1954.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 4187, 4188; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4187, 4188; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4187, 4188, 4190.

304223—54

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4181. Misbranding of Special Formula cream. U. S. v. 8 Jars * * *. (F. D. C. No. 35320. Sample No. 58957–L.)

LIBEL FILED: June 22, 1953, Western District of Michigan.

ALLEGED SHIPMENT: On or about March 31, 1952, by Bette Knowlton, from Miami, Fla.

PRODUCT: 8 jars of *Special Formula cream* at Grand Rapids, Mich. Examination showed that the article contained estrogenic hormones equivalent to 54,000 International Units (5.4 mg.) of estrone per ounce.

RESULTS OF INVESTIGATION: On or about March 23, 1952, the consignee received at Miami, Fla., from the Bette Knowlton Laboratories, a 26-page mimeographed booklet dated May 14, 1951, entitled "Bette Knowlton Reference Manual," to be used in the sale and use of the Bette Knowlton products. This booklet subsequently was transported by the consignee from Miami, Fla., to Grand Rapids, Mich. In addition, Bette Knowlton shipped from Miami, Fla., to Grand Rapids, Mich., on or about February 1, 1953, a number of leaflets entitled "Bette Knowlton Fortune In Loveliness" and one booklet entitled "Bette Knowlton Reference Notes."

LABEL, IN PART: (Jar) "Bette Knowlton Special Formula Cream 2 Oz. * * * Hormone & Vitamin A Formula. Contains Type A Natural Extrogenic Substance, 50,000 I. U. per oz., and Vitamin A, 10,000 units per oz."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, the jar label and the above-mentioned leaflets and booklets, since the labeling provided for the daily application of 1,800 International Units of estrogens as estrone over an extended and indefinite period of time, an amount which would cause injury to health.

DISPOSITION: July 9, 1953. Default decree of condemnation and destruction.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4182. Pyrilamine maleate-dextro-amphetamine sulfate. U. S. v. 187 Cartoned Vials * * *. (F. D. C. No. 35259. Sample No. 70469–L.)

LIBEL FILED: May 13, 1953, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 13, 1953, by Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 187 cartoned vials of *pyrilamine maleate-dextro-amphetamine sulfate* at Mansfield, Ohio. Analysis showed that the product contained essentially the amount of pyrilamine maleate stated on its label and 0.5 percent of phenol.

LABEL, IN PART: (Vial) "10 cc. Multiple-Dose Vial List No.: 1059 Pyrilamine Maleate-Dextro Amphetamine Sulphate Each cc. contains: Pyranisamine maleate 25 mg., Dextro Amphetamine Sulphate 2 mg."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: June 11, 1953. Default decree of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4183. Misbranding of dextro-amphetamine sulfate tablets and pentobarbital sodium capsules. U. S. v. Paul B. Ginther (Central Drug Co.). Plea of guilty. Fine of $625, plus costs. (F. D. C. No. 35101. Sample Nos. 48446–L, 48457–L to 48460–L, incl.)

INFORMATION FILED: August 19, 1953, Southern District of Iowa, against Paul B. Ginther, trading as the Central Drug Co., Clinton, Iowa.

NATURE OF CHARGE: On or about October 20 and November 14 and 15, 1952, while a number of *dextro-amphetamine sulfate tablets* and *pentobarbital sodium capsules* were being held for sale at the Central Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. This act of dispensing was contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: September 14, 1953. The defendant having entered a plea of guilty, the court fined him $625, plus costs.

4184. Misbranding of dextro-amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Roy G. Williams, Inc., Wilfred H. Thornton, William H. Taylor, and Bernard H. Parks. Pleas of guilty. Fine of $50 against each defendant. (F. D. C. No. 34870. Sample Nos. 2366–L, 2371–L, 2372–L, 2652–L, 2655–L.)

INFORMATION FILED: September 15, 1953, Middle District of Georgia, against Roy G. Williams, Inc., Macon, Ga., Wilfred H. Thornton, vice president and manager of the corporation, and William H. Taylor and Bernard H. Parks, pharmacists for the corporation.

NATURE OF CHARGE: On or about November 7, 11, and 12, 1952, while a number of *dextro-amphetamine sulfate tablets* and *Seconal Sodium capsules* were being held for sale at Roy G. Williams, Inc., after shipment in interstate commerce, various quantities of the drugs were dispensed upon requests for refills of written prescriptions for such drugs, without obtaining authorization by the prescriber. Roy G. Williams, Inc., and Wilfred H. Thornton were charged with causing the acts of dispensing in each of the 5 counts of the information; Bernard H. Parks was joined as a defendant in 3 of the counts; and William H. Taylor was joined as a defendant in the other 2 counts. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: September 29, 1953. Pleas of guilty having been entered, the court fined each defendant $50, a total fine of $200.

4185. Misbranding of dextro-amphetamine sulfate tablets, sulfisoxazole tablets, and phenobarbital tablets. U. S. v. Winton E. Bloodworth (Winton's Pharmacy), and Julian H. Wood. Pleas of guilty. Fine of $50 against each defendant. (F. D. C. No. 34873. Sample Nos. 2365–L, 2367–L, 2458–L, 2641–L, 2648–L, 2653–L.)

INFORMATION FILED: September 15, 1953, Middle District of Georgia, against Winton E. Bloodworth, trading as Winton's Pharmacy, Macon, Ga., and Julian H. Wood, pharmacist.

NATURE OF CHARGE: On or about October 22 and 31 and November 5, 7, and 12, 1952, while a number of *dextro-amphetamine sulfate tablets, sulfisoxazole*

tablets, and *phenobarbital tablets* were being held for sale at Winton's Pharmacy, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Winton E. Bloodworth was charged with causing the act of dispensing in each of the 6 counts of the information, and Julian H. Wood was joined as a defendant in 4 of the counts. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: September 29, 1953. The defendants having entered pleas of guilty, the court fined each defendant $50.

4186. Misbranding of Tuinal capsules, methamphetamine hydrochloride tablets, and dextro-amphetamine sulfate tablets. U. S. v. Charles C. Yeagle (Yeagle's Pharmacy), and Earl W. Clark. Pleas of guilty. Fine of $400 against Defendant Yeagle and $200 against Defendant Clark, plus costs. (F. D. C. No. 34330. Sample Nos. 12138–L, 12141–L, 12143–L, 36140–L, 36141–L, 56424–L.)

INFORMATION FILED: April 13, 1953, Eastern District of Kentucky, against Charles C. Yeagle, trading as Yeagle's Pharmacy, Covington, Ky., and Earl W. Clark, an employee.

NATURE OF CHARGE: On or about August 13, 14, 15, 16, and 20, 1952, while a number of *Tuinal capsules*, *methamphetamine hydrochloride tablets*, and *dextro-amphetamine sulfate tablets* were being held for sale at Yeagle's Pharmacy, after shipment in interstate commerce, various quantities of the drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. Charles C. Yeagle was charged with causing the act of dispensing in each of the 6 counts of the information, and Earl W. Clark was joined as a defendant in 4 of the counts. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: September 29, 1953. The defendants having entered pleas of guilty, the court fined Defendant Yeagle $400 and Defendant Clark $200, plus costs.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4187. Misbranding of methamphetamine hydrochloride tablets and methyltestosterone tablets. U. S. v. Arthur W. Williams (Earl Drug Store), and Karl F. Reynolds. Pleas of guilty. Fine of $15 against Defendant Reynolds and $150 against Defendant Williams. (F. D. C. No. 32735. Sample Nos. 15491–L to 15493–L, incl., 15497–L, 15498–L, 15504–L, 15505–L.)

INFORMATION FILED: June 12, 1953, Western District of Oklahoma, against Arthur W. Williams, trading as the Earl Drug Store, at Lawton, Okla., and Karl F. Reynolds, a pharmacist for the store.

ALLEGED VIOLATION: On or about October 11, 15, and 22, 1951, while a number of *methamphetamine hydrochloride tablets* and *methyltestosterone tablets* were being held for sale at the Earl Drug Store, after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded. Defendant Reynolds was charged with causing the acts of repackaging and dispensing involved in count 1 of the information and De-

fendant Williams was charged with causing the acts of repackaging and dispensing involved in the other 6 counts of the information.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *methamphetamine hydrochloride tablets* and a portion of the *methyltestosterone tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (2), a portion of the *methamphetamine hydrochloride tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug; and, Section 502 (f) (2), all of the repackaged *methamphetamine hydrochloride tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: June 12, 1953. Pleas of guilty having been entered, the court fined Defendant Reynolds $15 and Defendant Williams $150.

4188. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Granville V. Coots. Plea of nolo contendere. Fine, $1. (F. D. C. No. 31255. Sample Nos. 20928–L, 20930–L, 20954–L, 20956–L.)

INFORMATION FILED: June 26, 1953, Northern District of Texas, against Granville V. Coots, manager of Field's Cut Rate Drug Store, Dallas, Tex.

ALLEGED VIOLATION: On or about May 16 and 17, 1951, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at Field's Cut Rate Drug Store, after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use. Further misbranding, Section 502 (e) (1), portions of the repackaged tablets failed to bear labels containing the common or usual name of the drug.

DISPOSITION: September 24, 1953. The defendant having entered a plea of nolo contendere, the court fined him $1.

4189. Misbranding of Char-Co Compound. U. S. v. 56½ Cases, etc. (F. D. C. No. 35285. Sample No. 46469–L.)

LIBEL FILED: June 12, 1953, Southern District of Texas.

ALLEGED SHIPMENT: Between February 1 and April 30, 1953, from Maplewood, Mo.

PRODUCT: 56½ cases, each full case containing 12 12-ounce bottles, of *Char-Co Compound* at Houston, Tex., in the possession of K. G. Peters, together with a number of display posters entitled "Ask Your Druggist for" and a number of leaflets entitled "W. H. Peters Char-Co Compound * * * for Stomach Trouble."

RESULTS OF INVESTIGATION: The above-mentioned literature was printed for the consignee and was distributed by him to prospective customers (individuals) and to drug stores that stocked the product.

LABEL, IN PART: (Bottle) "W. H. Peters Char-Co Compound Treatment for Alleviation of Stomach Distress Symptoms Due to Excess Acid * * * Contents: Charcoal, Milk Magnesia, Magnesium Trisilicate, Aluminum Hydroxide Gel."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the above-mentioned display posters and in the leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for stomach ulcers and stomach trouble, whereas the article was not an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of stomach ulcers and stomach trouble, which were the conditions for which the article was intended.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: August 26, 1953. W. H. Peters, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4190. Misbranding of Magnetic Ray belt. U. S. v. 5 Devices, etc. (F. D. C. No. 35293. Sample No. 59163-L.)

LIBEL FILED: June 11, 1953, Southern District of Florida.

ALLEGED SHIPMENT: On or about April 29, 1953, from Coppell, Tex., by F. B. Moran, doing business as the Magnetic Ray Co.

PRODUCT: 5 unlabeled devices known as *Magnetic Ray belt* at St. Petersburg, Fla., in the possession of F. H. Squire, together with a number of testimonial letters accompanying the devices. The device consisted essentially of a circular coil of electric wire, with an electric plug attachment for plugging into the house current.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device, namely, the above-mentioned testimonial letters which were used by F. H. Squire to promote the sale and rental of the device, contained statements which were false and misleading. The statements represented and suggested that the device provided an adequate and effective treatment for headache, insomnia, impaired heart action, constipation, abnormal blood pressure, paralytic stroke, bad veins, epilepsy, tumors, lumbago, asthma, hardening of the arteries, arthritis, varicose veins, and tonsillitis. The device did not provide an adequate and effective treatment for such conditions. The device was misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (b) (1), the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (1), the device, when introduced into interstate commerce, was intended for use in the cure, mitigation, and treatment of disease in man, and it neither bore nor was accompanied by labeling bearing adequate directions for use since it had no labeling. The device was misbranded in these respects when introduced into and while in interstate commerce.

DISPOSITION: September 30, 1953. Default decree of condemnation. The court ordered that the devices and testimonial letters be delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4191. Adulteration of posterior pituitary injection. U. S. v. Cleo O. Bedwell. Plea of nolo contendere. Fine, $50. (F. D. C. No. 33778. Sample Nos. 17304-L, 17329-L.)

INFORMATION FILED: June 2, 1953, Southern District of California, against Cleo O. Bedwell, president of the Coast Chemical Co., a corporation, Los Angeles, Calif.

ALLEGED VIOLATION: On or about January 18 and May 1, 1952, the defendant caused to be given to firms engaged in the business of shipping drugs in interstate commerce, invoices containing guaranties to the effect that the *posterior pituitary injection* listed in the invoices and delivered by the defendant under the guaranties would not be adulterated. On or about January 18 and May 1, 1952, the defendant caused to be delivered to the holders of the guaranties, at Los Angeles, Calif., quantities of *posterior pituitary injections* which were adulterated.

LABEL, IN PART: (Vials) "Post Pituitary Solution U. S. P. * * * Towne, Paulsen & Co., Inc. Distributors Pasadena, Cal." and "Obstetrical Pituitary U. S. P. * * * Medical Specialties Co. Los Angeles, Calif."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Posterior Pituitary Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since each cubic centimeter of the article possessed an activity equivalent to less than 8.5 U. S. P. posterior pituitary units, whereas the standard provides that each cubic centimeter of posterior pituitary injection possesses an activity equivalent to not less than 8.5 U. S. P. posterior pituitary units; and the difference in strength of the article from the standard was not plainly stated, or stated at all, on its label.

DISPOSITION: August 17, 1953. The defendant having entered a plea of nolo contendere, the court fined him $50.

4192. Adulteration and misbranding of Yale Testrex tablets. U. S. v. Captivante Laboratories, Inc., and Paul Thomas. Pleas of guilty. Fine of $150 against corporation and $300 against individual. (F. D. C. No. 34860. Sample Nos. 32442-L, 32449-L, 34692-L.)

INFORMATION FILED: May 6, 1953, Southern District of New York, against Captivante Laboratories, Inc., New York, N. Y., and Paul Thomas, president of the corporation.

ALLEGED SHIPMENT: On or about March 28, April 22, and May 29, 1952, from the State of New York into the State of Arkansas.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess. Some of the tablets were represented to contain 2.5 milligrams of methyltestosterone and other tablets were represented to contain 5 milligrams of methyltestosterone, whereas the tablets contained less methyltestosterone than represented.

Misbranding, Section 502 (a), the label statements "Ingredients per tablet 2.5 mg. [or "5 mg."] Methyl-Testosterone" were false and misleading.

DISPOSITION: September 14, 1953. The defendants having entered pleas of guilty, the court fined the corporation $150 and the individual $300.

4193. Adulteration and misbranding of Merestrin tablets. U. S. v. 166 Bottles * * *. (F. D. C. No. 35329. Sample No. 72255–L.)

LIBEL FILED: June 22, 1953, District of Columbia.

ALLEGED SHIPMENT: On or about December 30, 1952, by Hance Bros. & White Co., from Philadelphia, Pa.

PRODUCT: 166 bottles of *Merestrin tablets* at Washington, D. C. Analysis showed that the product contained 74 percent of the declared amount of the estrogenic ingredient.

LABEL, IN PART: (Bottle) "100 S. C. Yellow Tablets Merestrin Tablets Each Yellow Tablet Contains: 1.25 mgs. of Estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess since the article contained but 74 percent of the declared amount of the estrogenic ingredient.

Misbranding, Section 502 (a), the label statement "Each Yellow Tablet Contains: 1.25 mgs. of Estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate" was false and misleading as applied to the article, which contained but 74 percent of the declared amount of conjugated estrogens calculated as sodium estrone sulfate.

DISPOSITION: July 22, 1953. Irwin T. Sealfon, trading as the Meredyth Co., Washington, D. C., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for reprocessing under the supervision of the Department of Health, Education, and Welfare. The tablets were reprocessed by washing for the removal of their coating and by regrinding for the adding of estrogens.

4194. Adulteration and misbranding of vitamin B complex. U. S. v. 225 Vials * * *. (F. D. C. No. 35447. Sample No. 62726–L.)

LIBEL FILED: August 4, 1953, Western District of Tennessee.

ALLEGED SHIPMENT: On or about May 1, 1953, by the Medical Chemicals Corp., from Chicago, Ill.

PRODUCT: 225 vials of *vitamin B complex* at Memphis, Tenn. Analysis showed that the product contained 73 percent of the declared amount of vitamin B_1 (thiamine hydrochloride).

LABEL, IN PART: "10 cc multiple dose sterile vial vitamin B complex Each cc contains: thiamine HCL. 100 mgs."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 100 milligrams of thiamine hydrochloride per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc contains: thiamine HCL. 100 mgs." was false and misleading as applied to the article, which contained less than 100 milligrams of thiamine hydrochloride per cubic centimeter.

DISPOSITION: September 9, 1953. Default decree of condemnation and destruction.

4195. Adulteration and misbranding of isopropyl alcohol rubbing compound. U. S. v. 199 Cases * * *. (F. D. C. No. 35075. Sample No. 47435–L.)

LIBEL FILED: June 9, 1953, Northern District of Mississippi.

ALLEGED SHIPMENT: On or about May 11, 1953, by F. Uddo & Sons Co., from New Orleans, La.

PRODUCT: 199 cases, each containing 12 bottles, of *isopropyl alcohol rubbing compound* at Tupelo, Miss.

LABEL, IN PART: "Sure-Rub * * * Isopropyl Rubbing Alcohol Compound Isopropyl Alcohol 70% * * * Contents One Pint."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Isopropyl Alcohol Rubbing Compound," a drug the name of which is recognized in the National Formulary, an official compendium, and the strength of the article differed from the official standard since it contained less than 68 percent isopropyl alcohol, the minimum permitted by the standard.

Misbranding, Section 502 (a), the label statement "Isopropyl Alcohol 70%" was false and misleading as applied to the article, which contained 47.8 percent isopropyl alcohol.

DISPOSITION: October 9, 1953. Default decree of condemnation. The court ordered that the product be delivered to State institutions for their use and not for sale.

4196. Adulteration and misbranding of rubber prophylactics. U. S. v. 16 Cases * * *. (F. D. C. No. 35072. Sample No. 62945–L.)

LIBEL FILED: June 5, 1953, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about April 27, 1953, by the Killashun Sales Div., from Akron, Ohio.

PRODUCT: 16 cases, each containing 40 gross, of *rubber prophylactics* at St. Louis, Mo. Examination of samples of the product showed that 3.1 percent were defective in that they contained holes.

LABEL, IN PART: "X-Cello's Prophylactics Mfd. By The Killian Mfg. Co. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactics" and "Sold for the Prevention of Disease Only" were false and misleading as applied to an article containing holes.

DISPOSITION: August 5, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4197. Misbranding of Hyzorbis tablets. U. S. v. 7 Bottles, etc. (F. D. C. No. 35340. Sample No. 55799–L.)

LIBEL FILED: June 29, 1953, Western District of Pennsylvania.

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*See also Nos. 4189, 4190, 4192–4196.

ALLEGED SHIPMENT: On or about March 6, April 22, and May 8, 1953, by Walker Corp. & Co., Inc., from Syracuse, N. Y.

PRODUCT: 7 1,000-tablet bottles and 5 2,000-tablet bottles of *Hyzorbis tablets* at Pittsburgh, Pa.

LABEL, IN PART: (Bottle) "Hy-Zorbis Gastro-Enteric Sedative * * * Hyzorbis represents in each tablet Extract Hyoscyamus ¼ gr. (16.2 mg.) (containing 0.0003875 gr. total alkaloids of Hyoscyamus), Bismuth Subcarbonate 2 gr. (129.6 mg.), Magnesium Trisilicate 2 gr. (129.6 mg.), Calcium Carbonate 1 gr. (64.8 mg.), Magnesium Carbonate 1 gr. (64.8 mg.) and Diastase ¼ gr. (16.2 mg.)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for disturbances of the gastrointestinal tract, such as gastroenteritis, mucous colitis, dysentery, diarrhea, and peptic and duodenal ulcers. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: August 6, 1953. Default decree of condemnation. The court ordered that the product be delivered to a county institution.

4198. Misbranding of Amerpol tablets. U. S. v. 4 Display Cartons * * *. (F. D. C. No. 35341. Sample No. 55141–L.)

LIBEL FILED: June 29, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about April 23, 1953, by Amerpol Associates, from Chicago, Ill.

PRODUCT: 4 display cartons, each containing 12 bottles, of *Amerpol tablets* at Milwaukee, Wis.

LABEL, IN PART: (Display carton) "Amerpol Tablets"; (bottle) "Amerpol Formula An aid for the relief of minor pains & aches due to medically diagnosed Arthritis, Rheumatism, Neuritis, Sciatica, Lumbago, Bursitis, Neuralgia and Sinus Headaches * * * 100 Tablets * * * Active Ingredients: Salicylamide, Calcium Succinate, Dalamine (brand of mixture of Magnesium Hydroxyaminoacetate and Aluminum Hydroxide). Also each tablet contains and supplies the following percentages for: 1 mg. Vitamin B_1 (Thiamin Chloride) 100% M.D.R. 5 mg. Vitamin C (Ascorbic Acid) 16% M.D.R."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and on an accompanying circular printed in Polish and entitled "Amerpol Tabletki * * * Artretyzm i Reumatyzm," which were kept on a counter near a display of the above-mentioned product handy for handing out to customers, were false and misleading. These statements represented and suggested that the article was an adequate and effective treatment for arthritis, rheumatism, neuritis, sciatica, lumbago, bursitis, neuralgia, and sinus conditions, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: July 31, 1953. Default decree of condemnation and destruction.

4199. Misbranding of Miracold device and Miracold drug. U. S. v. 58 Cartoned Devices, etc. (F. D. C. No. 35292. Sample No. 27434–L.)

LIBEL FILED: June 15, 1953, Northern District of California.

ALLEGED SHIPMENT: On or about January 9, February 7, and September 15, 1951, by Miracold, Inc., from Seattle, Wash.

PRODUCT: 58 cartoned devices known as *Miracold dispenser* and 2 8-ounce bottles of a drug known as *Miracold* at San Francisco, Calif.

LABEL, IN PART: (Carton) "Model B The Little M.D. Miracold Dispenser Read Instructions Designed To Combat The Common Cold, The Flu And Many Other Airborne Diseases. The Little M.D. Vaporizes Miracold"; (bottle) "Contents 8 Fluid Oz. Miracold Active Ingredient 100% Triethylene Glycol For Use In The Little MD Miracold Dispenser."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton label and on the leaflet enclosed in each carton entitled "The Miracle of Miracold 'The Little M.D.'" were false and misleading. The statements represented and suggested that the device and the drug provided an adequate and effective treatment for colds, influenza, respiratory ailments, and breathing discomfort, and for preventing those conditions. The device and the drug did not provide an adequate and effective treatment or preventive for such conditions.

DISPOSITION: September 10, 1953. Default decree of condemnation and destruction.

4200. Misbranding of Dr. Keller's Electron Dispersion shoes. U. S. v. 19 Pairs * * *. (F. D. C. No. 35316. Sample No. 53580–L.)

LIBEL FILED: On or about June 19, 1953, Western District of Missouri.

ALLEGED SHIPMENT: On or about April 8 and June 12, 1952, from Paducah, Ky.

PRODUCT: 19 pairs of *Dr. Keller's Electron Dispersion shoes* for women at Sedalia, Mo., in the possession of Roy M. Keller, D. C., together with a number of booklets entitled "The Electronic Factor in Bodily Function," a number of yellow leaflets entitled "Dr. Keller's Electron Dispersion Shoe," and a number of white leaflets entitled "Electron Dispersion Research."

RESULTS OF INVESTIGATION: The above-mentioned booklets and leaflets were printed locally for the consignee and distributed to prospective customers. The yellow leaflet described the shoes as follows: "The lining is of conductive material which is connected through the heel to the sole, which is a rubber like * * * conductive material."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets and leaflets accompanying the shoes were false and misleading. The statements represented and suggested that the shoes, by dispersing body electricity, would promote good health; that they would prevent interference with normal functions of the body, predisposition to disease, arthritis, rheumatism, neuritis and other conditions preceding and during storms, tiredness, and aching of the feet; that they would effect helpful results in specific ailments; and that they would contribute to the maintenance of buoyant health and would improve health. The shoes were not capable of fulfilling the promises made for them. The shoes were misbranded in the above respect while held for sale after shipment in interstate commerce.

DISPOSITION: July 29, 1953. A default decree was entered providing for the destruction of the booklets and leaflets and the delivery of the shoes to a charitable organization.

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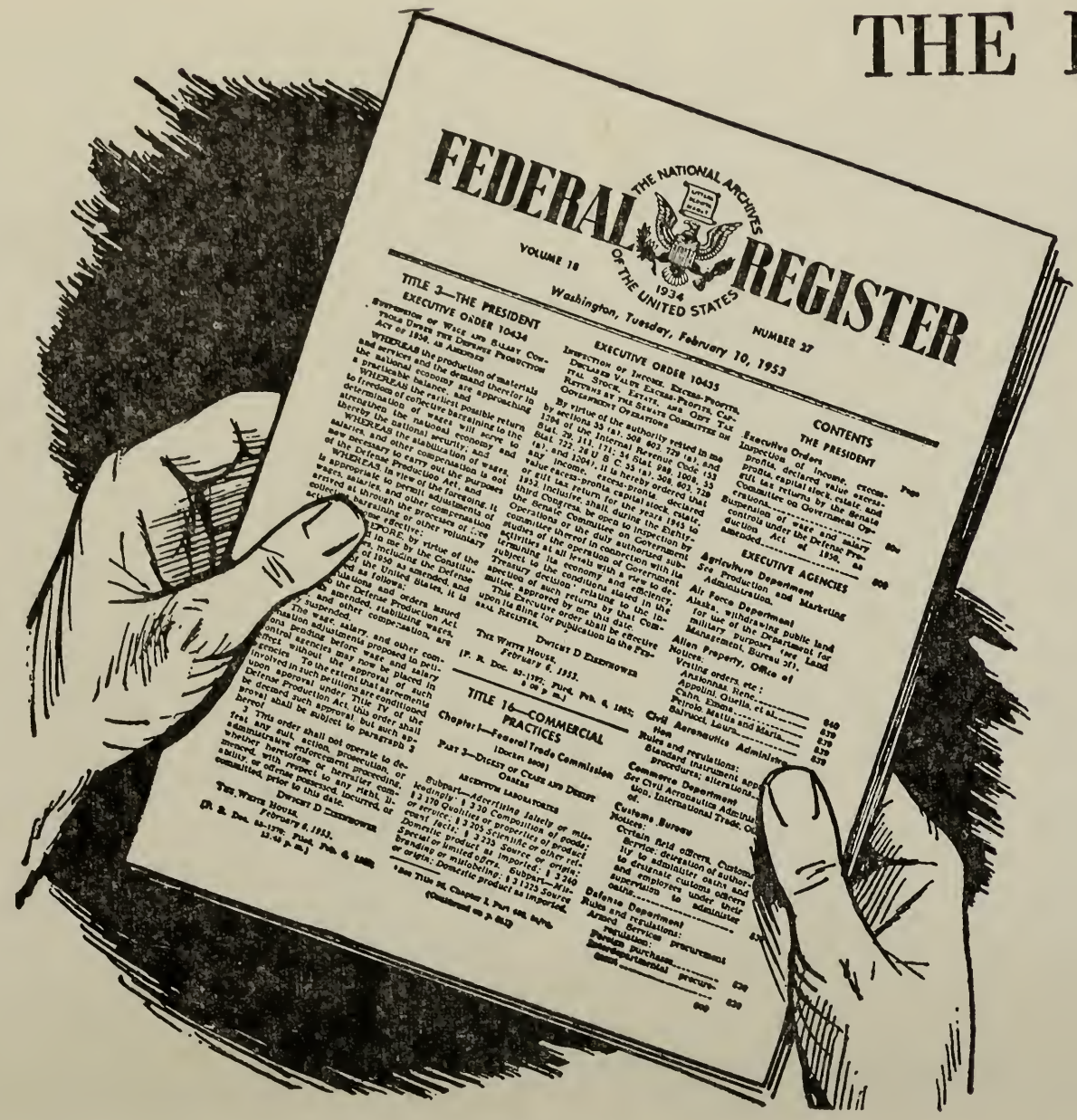

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4201–4220

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *August 27, 1954.*

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*For presence of a habit-forming narcotic without warning statement, see No. 4209; omission of, or unsatisfactory, ingredients statements, Nos. 4209, 4210; failure to bear a label containing an accurate statement of the quantity of contents, Nos. 4209, 4210; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4209.

306996—54

DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4201. Misbranding of La Parfaite syringe. U. S. v. 161 Devices, etc. (F. D. C. No. 33280. Sample No. 1159–L.)

LIBEL FILED: On or about June 12, 1952, Southern District of Florida.

ALLEGED SHIPMENT: On or about November 16, 1950, from Paris, France.

PRODUCT: 161 *La Parfaite syringes* in individual boxes at Highland City, Fla., together with a number of circulars entitled "Feminine Hygiene is made 100% Effective."

The device consisted of a porcelain fitting equipped with a rubber inlet tube and a rubber outlet tube. The rubber inlet tube had a number of openings near the tip and one opening at the very tip end. In operation, a supply of fluid under hydrostatic pressure would be forced into the vagina through the rubber inlet tube.

RESULTS OF INVESTIGATION: Upon receipt of the devices from France, the consignee, Mrs. Grace Kern, doing business as the Florida Hygienic Co., at Highland City, Fla., repackaged the devices into individual boxes, together with 1 copy of the above-mentioned circular which had been printed for the consignee.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned circular were false and misleading. The statements represented and suggested that use of the device was effective for insuring a sound, healthy body for women, enabling the penetration of a cleansing solution to all parts of the vaginal tract, preventing cancer which might be caused by bruising the uterus through use of other types of douching devices, and providing a safe method of douching. The device was not effective for the intended purposes, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling since the jet of fluid emerging from the hole in the tip of the device would enter the uterus and cause injury.

The device was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: November 16, 1953. Grace Kern, claimant, having filed an answer to the libel and later having withdrawn such answer, judgment of condemnation was entered and the court ordered that the devices and the labeling be destroyed.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4202. Misbranding of pulvules containing a mixture of Seconal Sodium and Amytal Sodium. U. S. v. Arnold's Pharmacy, Inc., Richard Leipert, and Max Rosenthal. Motion denied to dismiss information and to suppress evidence. Plea of guilty. Fine of $3 against corporation and $300 against each individual. (F. D. C. No. 35098. Sample Nos. 37495–L, 37497–L, 37500–L.)

INFORMATION FILED: May 28, 1953, District of New Jersey, against Arnold's Pharmacy, Inc., Newark, N. J., Richard Leipert, treasurer of the corporation, and Max Rosenthal, pharmacist.

NATURE OF CHARGE: On or about October 21 and 28 and November 6, 1952, while a number of *pulvules containing a mixture of Seconal Sodium and Amytal Sodium* were being held for sale at Arnold's Pharmacy, Inc., after shipment in interstate commerce, the defendants caused various quantities of the drug to be dispensed upon requests for refills of a written prescription therefor without obtaining authorization by the prescriber. Such acts of dispensing were contrary to Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: A motion to dismiss the information and to suppress evidence was filed on behalf of the defendants, and, on November 5, 1953, the court handed down the following opinion in denial of such motion:

HARTSHORNE, *District Judge:* "The defendants, Arnold's Pharmacy, Inc., a corporation, Richard Leipert, its Treasurer and Manager, and Max Rosenthal, its pharamacist, were all indicted for violating the Pure Food, Drug and Cosmetic Act, commonly known as the Pure Food and Drug Act, as amended June 25, 1938, chapter 675, 52 Stat. 1040, Title 21 U. S. C. A. Supp. Section 301, et seq. Specifically, Count 1 of the Information charged defendants with a certain sale of Seconal Sodium and Amytal Sodium, after shipment in interstate commerce, such drugs being dispensable only on physician's prescription, but being sold by the defendants without such prescription or physician's authorization. Counts 2 and 3 are identic with Count 1, save that they allege similar sales on other dates. All defendants moved to dismiss the Information, as confusing, ambiguous, indefinite, and as founded upon evidence illegally obtained. Defendants also moved to suppress and return the evidence as being seized in violation of the corporation's constitutional rights, i. e., as an unreasonable search and seizure under the Fourth Amendment, and as a violation of the immunity clause in the statute itself, ibid. Section 373.

THE MOTION TO DISMISS

"The statute clearly is intricate. Indeed, the Supreme Court has recently found a certain portion of the statute Section 301 (f), Title 21 U. S. C. A. Food and Drug, Section 331 (f) invalid, as vague and not giving 'fair warning,' in view of its apparent contrariety with Section 704 (Title 21 U. S. C. A. Section 374). U. S. v. Cardiff, 344 U. S. 174 (1952). But such sections are not here involved. Moreover, the basis of the *Cardiff* decision as to the statutory provisions there in question is lacking as to the statutory provisions here involved. In *Cardiff* the Court found that the necessity for the Government to obtain from the owner of the premises his voluntary permission to enter was inexplicable, in view of the penalization, in another portion of the statute, of the owner's refusal to grant such permission. But in the case at bar, as will later appear, no such voluntary permission to enter is connected with the statutory provision in question.

"The differing charge in this case is the sale of a 'habit-forming drug to which Section 352 [502] (d) of this Title applies,' contrary to Section 353 [503] (b) (1) (A), in that it was to be dispensed only upon a written prescription of a physician, but in fact was dispensed without any such authorization; that accordingly same was a statutory 'misbranding,' misbrandings being a violation of the Act under Section 331 (k), the penalties for such misbrandings being set forth in Section 333 (a). When read with care, such statutory provisions appear neither vague nor contradictory, the allusion to Section 352 [502] (d) being merely descriptive of the character of the drug, and not constituting a separate offense from that set forth above.

"The motion to dismiss is denied.

THE MOTION TO SUPPRESS EVIDENCE

"A series of affidavits as to the facts underlying the Government's obtaining of this evidence were filed by both sides. While contradictory in part, the truth obviously lies in the oral testimony of the Newark Police Officer, Duffy, who was not only present at the time of the sale and the first search, but who, because he had been a former clerk of defendant corporation, refused

to give the Government an affidavit as to the facts he knew, which forced the Government to subpoena him, and take his testimony orally at the time of the argument on the motion. Indeed, the confidence of the defendants in this officer, their former clerk, even after this sale and seizure, is evidenced by the fact that these defendants themselves got the officer to return later to help them complete, themselves, the search of their records, initiated after the sale. Officer Duffy testifies that, though he happened to be in the pharmacy, in uniform, at the time of the sale, and at the very time the samples and prescription records were first made available to the Government's agents, there was no remonstrance whatever on defendants' part to turning over these samples and shipping records. Nor did he hear the Government's agents, as claimed, tell the defendants to 'read the law,' in reply to a claimed remonstrance on defendants' part. It is obvious that this old friend, in a police uniform, embodied the law to the defendants at the time, and that, had they any thought of objecting to turning over the evidence, they would most certainly have appealed to him for aid. Since they did not do so, it is therefore clear that they willingly turned over the samples, the shipping and other records, as the Government's affidavits say, as well as willingly signing certain statements, and permitting certain photographs to be taken.

"Such being the case, it is perfectly clear that there was no violation of the constitutional rights of the defendant corporation, the owner, as claimed, since such search occurred with the full voluntary permission of defendant Leipert, the Manager of the corporate defendant. Zap v. U. S., 328 U. S. 624 (1946). We turn, then, to the question of whether this evidence was 'obtained under this section' of the law, Title 21 U. S. C. A. Food and Drugs Section 373. For, if it was, that section of the statute expressly provides that same 'shall not be used in a criminal prosecution of the person from whom obtained,' this person meaning both the corporate owner and the individual from whom same was obtained.

"Defendant claims that this evidence, at least the shipping records, and the prescription records, were obtained by virtue of these statutory provisions. The Government claims, on the contrary, that they were obtained, not by virtue of the statute, but by virtue of the permission granted by the corporate owner and its authorized agent. The meaning of this section of the statute is thus in question.

"The meaning of an ambiguous statutory provision [1] is best considered first from the standpoint of those who enacted it. Thus we turn to the purpose of the statute. The report of the committee upon the basis of which the 1938 amended act was adopted, 75th Congress, 3d Session, Report 2139, Food, Drug and Cosmetic Act, April 14, 1938, states, in pertinent part '* * * While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. * * * The measure contains substantially all the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception * * *. Carriers are required to make, available for copying, records showing interstate shipments of suspected articles so that Federal jurisdiction can be established * * *. Section 703 (373) requires interstate carriers and receivers to permit access to and the copying of all necessary records to show interstate shipment and thus establish Federal jurisdiction. This provision is necessary

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[1] § 373. Records of interstate shipment.

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Administrator, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: Provided, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: Provided further, That carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers. June 25, 1938, c. 675, § 703, 52 Stat. 1057; Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 Fed. Reg. 2422, 54 Stat. 1237.

since some warehousemen and trucking concerns and even some railroads have refused to permit the copying of records which were essential to the institution of proceedings to control abuses of consumer health and welfare. The absence of such provision in the present law has been a definite handicap to its enforcement. * * *.'

"In short, the purpose of the provision here in question was to close an earlier loophole in the enforcement provisions of the act, which handicapped its enforcement, this handicap being caused by the refusal of certain carriers, if not others, to permit the copying of essential records. In other words, where, as was generally the case, these records were willingly made available to the Government, so that the Act could readily be enforced, the previous law was effective. But, in cases where this access and copying was refused, the section in question would apply to overcome such refusal, and eliminate such 'handicap to its (the Act's) enforcement.'

"The purpose of the statutory provision was thus to cover cases where the Government was refused access and copying of records. Not only is this clear from a consideration of the Congressional purpose, but the language of the section itself expresses such purpose. That is why the section states that carriers and persons receiving drugs 'shall' permit a governmental officer 'to have access to and to copy all records showing the movement in interstate commerce' and the 'holding thereof * * * after such movement.' That is why the section in question further provides that, if the Government officer not only requests such permission, but accompanies it with a written specification of the drug requested, 'it shall be unlawful for any such carrier or person to fail to permit such access to and copying * * *.' In short, if the person holding the drug and the records refuses access and copying, the statute makes it mandatory upon him to accede, and if he fails to accede after being served such a statement in writing, he is subject to a specific penalty. Title 21 U. S. C. A. Food and Drugs Section 331 (e).

"Considered, therefore, in the light of both the purpose of this statutory amendment and of its terms, it is clear that it is not intended to hamper the powers of the Government in protecting the public, but to add to its powers to that end. Thus since, under well settled principles, those who voluntarily turn over their records to the Government cannot object to their use in criminal proceedings, it can hardly be claimed that this statutory amendment was intended to prevent such use under such circumstances. On the other hand, it is clear both from the purpose of the amendment and its terms, that the section was intended to apply where access to the records was refused the Government. In that event, by proceeding under the statutory provision in question, the Government could obtain access to such records despite such refusal. But, if the Government did so proceed, then the 'evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.'

"Not only does the above seem clear on reason, but it has the support of authority. In U. S. v. Crescent-Kelvan Co., (3 Cir. 1948) 164 F. 2d 582, 586, the Court specifically held that interstate shipping records were lawfully taken by the Government agents. Although the opinion in the main discussed a taking of samples under Section 374, that it was also concerned with section 373, in question here, is apparent from its allusion thereto in footnote 4. This upholding of the taking in *Crescent-Kelvan* was based upon the fact that 'permission to make such an inspection was implicitly granted to them by the individual defendants then present, who had the right to bind the "trust," ' the other defendant. Again, the section in question has been held to afford the Government a 'cumulative procedure * * * without restricting other avenues of information.' U. S. v. 75 Cases, etc. (4 Cir. 1944) 146 F. 2d 124, 127. In short, both these cases clearly recognize the fact that a lawful taking in such situations as the present may occur not only in cases of refusal, when the specific statutory requirements are met, but also in cases of permission, when general constitutional requirements are met. Indeed, the Pure Food and Drug Act itself apparently refers to this common law method of obtaining evidence as being in addition to that set forth in Section 373, since another section, Title 21 U. S. C. A. Food and Drug, Section 372 (a), authorizes the Government 'to conduct examinations and investigations for the purposes of this chapter' generally.

"Since the evidence here was voluntarily turned over to the Government by its owners, the conditions for the applicability of the statutory provision in

question did not exist, and the statute does not apply. And since the evidence was not obtained unconstitutionally, defendants' motion for the suppression, impounding and return of the evidence, is denied."

On January 15, 1954, the defendants entered pleas of guilty, and on March 5, 1954, the court fined the corporation $3 and each individual $300.

4203. Misbranding of Seconal Sodium capsules and tablets containing a mixture of crystalline potassium penicillin G and sodium citrate. U. S. v. Aaron Coleman (Coleman's Drug Store). Plea of guilty. Sentence of 6 months in jail and fine of $1,000. (F. D. C. No. 35107. Sample Nos. 37948–L, 37951–L, 37954–L, 50972–L, 50973–L.)

INFORMATION FILED: June 19, 1953, District of New Jersey, against Aaron Coleman, trading as Coleman's Drug Store, Newark, N. J.

NATURE OF CHARGE: On or about October 16, 17, and 21, and November 5, 1952, while a number of *Seconal Sodium capsules* and *tablets containing a mixture of crystalline potassium penicillin G and sodium citrate* were being held for sale at Coleman's Drug Store, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: October 1, 1953. The defendant having entered a plea of guilty, the court sentenced him to 1 year in jail and fined him $1,000. On October 14, 1953, the jail sentence against the defendant was reduced from 1 year to 6 months.

4204. Misbranding of Seconal Sodium capsules. U. S. v. Junior Amos. Plea of guilty. Fine of $500 or sentence of 60 days in jail. (F. D. C. No. 33767. Sample No. 4232–L.)

INFORMATION FILED: December 18, 1952, District of Columbia, against Junior Amos, Washington, D. C.

NATURE OF CHARGE: On or about December 13, 1952, the defendant sold a number of *Seconal Sodium capsules* in violation of Section 503 (b) (1), which requires that such habit-forming drug as Seconal be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

DISPOSITION: December 18, 1952. The defendant having entered a plea of guilty, the court sentenced the defendant to pay a fine of $500 or to serve 60 days in jail.

4205. Misbranding of tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfamethazine. U. S. v. Reginald Doyle Groves (Groves Pharmacy). Plea of guilty. Defendant fined $500 and placed on probation for 5 years. (F. D. C. No. 35121. Sample No. 37398–L.)

INFORMATION FILED: June 18, 1953, District of New Jersey, against Reginald Doyle Groves, trading as Groves Pharmacy, Newark, N. J.

NATURE OF CHARGE: On or about December 18, 1952, while a number of *tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfamethazine* were being held for sale at Groves Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such act of dispensing was contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed tablets being misbranded while held for sale.

DISPOSITION: October 30, 1953. The defendant having entered a plea of guilty, the court fined him $1,000 and sentenced him to serve 6 months in jail. On November 19, 1953, the court reduced the fine to $500 and substituted a 5-year period of probation for the jail sentence.

4206. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Mettery Sherry, Sr. (Sherry's Pharmacy). Plea of nolo contendere. Fine, $500. (F. D. C. No. 35099. Sample Nos. 46718–L, 46719–L.)

INFORMATION FILED: June 2, 1953, Eastern District of Louisiana, against Mettery Sherry, Sr., trading as Sherry's Pharmacy, New Orleans, La.

NATURE OF CHARGE: On or about January 21 and February 5, 1953, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at Sherry's Pharmacy, after shipment in interstate commerce, the defendant caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such act of dispensing was contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: August 26, 1953. The defendant having entered a plea of nolo contendere, the court fined him $500.

4207. Misbranding of dextro-amphetamine sulfate tablets and phenobarbital tablets. U. S. v. William E. McIntosh (W. E. McIntosh). Plea of guilty. Fine, $100. (F. D. C. No. 34837. Sample Nos. 61125–L to 61127–L, incl., 61129–L.)

INFORMATION FILED: May 14, 1953, Eastern District of Oklahoma, against William E. McIntosh, trading as W. E. McIntosh, Caddo, Okla.

NATURE OF CHARGE: On or about October 2, 4, and 6, 1952, while a number of *dextro-amphetamine sulfate tablets* and *phenobarbital tablets* were being held for sale at the W. E. McIntosh Drug Store, Caddo, Okla., the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: October 2, 1953. The defendant having entered a plea of guilty, the court fined him $100.

4208. Misbranding of methamphetamine hydrochloride tablets, dextro-amphetamine sulfate tablets, and secobarbital sodium capsules. U. S. v. Snyder-Jones Pharmacy, Inc., Paul Jones, Sr., and Paul Jones, Jr. Pleas of guilty. Fine of $1,500 against defendants jointly. Paul Jones, Sr., placed on probation for 18 months. (F. D. C. No. 34333. Sample Nos. 35696–L, 35697–L, 35699–L, 35700–L.)

INFORMATION FILED: On or about April 13, 1953, Eastern District of Tennessee, against Snyder-Jones Pharmacy, Inc., Johnson City, Tenn., and Paul Jones, Sr., president of the corporation, and Paul Jones, Jr., an employee.

NATURE OF CHARGE: On or about July 14 and 15, 1952, while a number of *methamphetamine hydrochloride tablets*, *dextro-amphetamine sulfate tablets*, and *secobarbital sodium capsules* were being held for sale at the Snyder-Jones Pharmacy, Inc., after shipment in interstate commerce, various quantities of the *methamphetamine hydrochloride tablets* were dispensed without a prescription from a practitioner licensed by law to administer such drug, and various quantities of *dextro-amphetamine sulfate tablets* and *secobarbital*

sodium capsules were dispensed upon request for refills of written prescriptions for such drugs without obtaining authorization from the prescriber. The corporation and Paul Jones, Sr., were charged with causing the acts of dispensing in each of the four counts of the information, and Paul Jones, Jr., was joined as a defendant in three of the counts. Such acts of dispensing were contrary to the provisions of Section 503 (b) 1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: October 1, 1953. Pleas of guilty having been entered, the court imposed a fine of $1,500 against the defendants jointly and placed Paul Jones, Sr., on probation for 18 months.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4209. Adulteration and misbranding of various drugs. U. S. v. 71 Bottles, etc. (F. D. C. No. 34477. Sample Nos. 41211–L to 41219–L, incl.)

LIBEL FILED: January 16, 1953, Western District of Washington.

ALLEGED SHIPMENT: On various dates after August 4, 1951, from points outside of the State of Washington.

PRODUCT: 71 bottles, each containing 1,000 tablets, of *Dex-Amo tablets;* 2 bottles, each containing 500 tablets, and 13 bottles, each containing 1,000 tablets, of *Paba-Sal tablets;* 13 bottles, each containing 1,000 capsules, of *Dasil Evronal capsules;* 4 bottles, each containing 1,000 2½-milligram tablets, and 5 bottles, each containing 1,000 5-milligram tablets, of *Desoxyephedrine hydrochloride tablets;* 29 unlabeled bottles, each containing 1,000 tablets, and 1 unlabeled bottle, containing 2,500 tablets, of a *drug presumed to be dextro-amphetamine sulfate tablets;* 3 bottles, each containing 1,000 tablets, of *amphetamine sulfate tablets;* 2 bottles, each containing 1,000 tablets, of *Dasil veratrum compound tablets;* and 11 bottles, each containing 1,000 tablets, of a *mixture of phenobarbital, aminophylline, and rutin,* at Seattle, Wash.

LABEL, IN PART: "No. 146 Dex-Amo Each tablet contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital NF ½ gr. (32 mg.) Distributed by Palmer & Co. Seattle, Wash."; "Tablets No. 137 Paba-Sal Each tablet contains Para-Aminobenzoic Acid (5 gr.) 0.3 gm. (as the Sodium Salt) Sodium Salicylate (5 gr.) 0.3 gm. Enteric Coated Distributed by Palmer & Co. Seattle, Wash. Average Adult Dose: Two tablets three times daily or as directed by physician"; "Dasil Evronal 1½ gr. Each capsule contains: Sodium Allyl-Isopropyl-Barbiturate . . . 1½ gr. (Sodium Aprobarbital) Palmer & Co. Distributors * * * Caution: To be dispensed only by or on the prescription of a physician"; "No. 125 Each tablet contains: d-Desoxyephedrine Hydrochloride 2.5 mgm. Distributed by Palmer & Co. Seattle, Wash. Caution: To be dispensed only by or on the prescription of a physician"; "No. 150 Each tablet contains: d-Desoxyephedrine Hydrochloride 5 mgm. Distributed by Palmer & Co. Seattle, Wash. Caution: To be dispensed only by or on the prescription of a physician"; " 5 Mg. Each Racemic Amphetamine Sulfate * * * Caution: To be dispensed only by or on the prescription of a physician Distributed By Palmer & Co. Seattle, Wash."; "Dasil Veratrum Compound Tablets Each tablet contains: Veratrum Viride ¾ gr. Phenobarbital ¼ gr. Sodium Nitrite 1 gr. Palmer & Co. Distributors"; and "No. 108 Each tablet contains: Phenobarbital . . . 15 mg. Aminophylline . . . 100 mg. Rutin . . . 20 mg. Warning: May be Habit Forming Distributed by Palmer & Co. Seattle, Wash. Caution: To be dispensed only by or on the prescription of a physician."

NATURE OF CHARGE: *Dex-Amo tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, (on label) "Each tablet contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital NF ½ gr. (32 mg.)," since each tablet contained less than the stated amount of such ingredients. Misbranding, Section 502 (a), the label statements "Each tablet contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital NF ½ gr. (32 mg.)" were false and misleading as applied to the article, which contained less than the declared amounts of dextro-amphetamine sulfate and amobarbital; and, Section 502 (b) (1), the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor, since the name of the city, Seattle, Wash., which appeared on the label unaccompanied by a street address, did not reveal the firm's place of business, and the firm's street address was not shown in the current city directory or telephone directory. Further misbranding, Section 502 (d), the article contained amobarbital, a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Paba-Sal tablets. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purpose for which the article was to be used.

Dasil Evronal capsules. Misbranding, Section 503 (b) (4), the article was a habit-forming drug to which Section 502 (d) applied, and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Desoxyephedrine hydrochloride tablets (2½-milligram and 5-milligram tablets), and *amphetamine sulfate tablets.* Misbranding, Section 502 (b) (1), the articles failed to bear labels containing the place of business of the manufacturer, packer, or distributor, since the name of the city, Seattle, Wash., which appeared on the label unaccompanied by a street address, did not reveal the firm's place of business, and the firm's street address was not shown in the current city directory or telephone directory; and, Section 503 (b) (4), the articles were drugs which, because of toxicity and other potentiality for harmful effect and the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Drug presumed to be dextro-amphetamine sulfate tablets. Misbranding, Section 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the article failed to bear a label containing the quantity or proportion of its active ingredient, dextro-amphetamine; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 503 (b) (4), the article was a drug which, because of toxicity and other potentiality for harmful effect and the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Dasil veratrum compound tablets. Misbranding, Section 502 (d), the article contained phenobarbital, a chemical derivative of barbituric acid, which

derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear in juxtaposition with the name, and quantity or proportion of such derivative the statement "Warning—May be habit forming." Further misbranding, Section 502 (a), the label designation "Veratrum Compound Tablets" was misleading as applied to the article, which contained in addition to veratrum other potent ingredients.

Tablets containing a mixture of phenobarbital, aminophylline, and rutin. Misbranding, Section 502 (d), the article contained phenobarbital, a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear in juxtaposition with the name, and quantity or proportion of such derivative the statement "Warning—May be habit forming." Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor, since the name of the city, Seattle, Wash., which appeared on the label unaccompanied by a street address, did not reveal the firm's place of business, and the firm's street address was not shown in the current city directory or telephone directory; and, Section 503 (b) (4), the article was a habit-forming drug to which Section 502 (d) applied, and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The *Dex-Amo tablets* were alleged to be adulterated and misbranded and the *Paba-Sal tablets* and the *Dasil veratrum compound tablets* were alleged to be misbranded as described above when introduced into and while in interstate commerce. The other drugs involved were alleged to be misbranded under Section 503 (b) (4), as stated above, while held for sale after shipment in interstate commerce. The 2½-milligram and the 5-milligram *desoxyephedrine hydrochloride tablets, amphetamine sulfate tablets, drug presumed to be dextro-amphetamine sulfate tablets,* and *tablets containing a mixture of phenobarbital, aminophylline, and rutin* also were alleged to be misbranded under other sections of the Act, as stated above, when introduced into and while in interstate commerce.

DISPOSITION: July 24, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4210. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Alan W. Saul (Saul's Pharmacy). Plea of nolo contendere. Fine, $450. (F. D. C. No. 33724. Sample Nos. 3516–L to 3518–L, incl.)

INFORMATION FILED: July 22, 1953, Eastern District of Virginia, against Alan W. Saul, trading as Saul's Pharmacy, Norfolk, Va.

ALLEGED VIOLATION: On or about February 20 and 27 and March 7, 1952, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at Saul's Pharmacy after shipment in interstate commerce, the defendant caused a number of such tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), the label of the article failed to bear the com-

*See also No. 4209.

mon or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: November 16, 1953. The defendant having entered a plea of nolo contendere, the court fined him $450.

4211. Misbranding of dried herbs. U. S. v. Charles E. Farley (Botanical & Marine Laboratories). Motion denied to dismiss information. Plea of nolo contendere. Sentence of 3 months in prison suspended and defendant placed on probation for 2 years. (F. D. C. No. 33762. Sample Nos. 5261–L, 5262–L, 5270–L, 6111–L.)

INFORMATION FILED: April 6, 1953, District of New Hampshire, against Charles E. Farley, trading as Botanical & Marine Laboratories, Manchester, N. H.

ALLEGED SHIPMENT: On or about December 30, 1950, and January 30, February 16, and November 9, 1951, from the State of New Hampshire into the States of Maine and Massachusetts.

LABEL, IN PART: "The Genuine Abbe Hamon Tea prepared By Botanical and Marine Laboratories * * * Formula No. 6 [or "Formula No. 11"]," "Abbe Hamon Formula Compounded and Packed In U. S. A. By Botanical and Marine Laboratories * * * Formula No. 1," and "The Genuine Abbe Hamon * * * Formula No. 13."

NATURE OF CHARGE: *Abbe Hamon Formula No. 1.* Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading. The statements represented and suggested that the article would be an adequate and effective treatment for diabetes; that it would enable organs of the body which refuse to perform their usual functions to again operate normally; and that it would heal illnesses and correct organic disorders brought about by daily abuse during months and years. The article would not be an adequate and effective treatment for diabetes, and it would not accomplish the results claimed. Further misbranding, Section 502 (f) (1), the directions for use appearing in the labeling of the article were not adequate for use in the treatment of diabetes; to enable organs of the body which refuse to perform their usual functions to again operate normally; and to heal illnesses and correct disorders brought about by daily abuse during months and years, which were the conditions and symptoms for which the article was prescribed, recommended, and suggested in its labeling.

Abbe Hamon Formula No. 6. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading. The statements represented and suggested that the article would be an adequate and effective treatment for epilepsy, all diseases of the nerves, neuralgia, insomnia, eclampsia, chorea, hysteria, and neurasthenia. The article would not be an adequate and effective treatment for such diseases and conditions. Further misbranding, Section 502 (f) (1), the directions for use appearing in the labeling of the article were not adequate for use in the treatment of the ailments and conditions for which the article was prescribed, recommended, and suggested in its labeling.

Abbe Hamon Formula No. 11. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading. The statements represented and suggested that the article would be an effective and adequate treatment for obesity, paralysis, goiter, and arteriosclerosis; that it would enable organs of the body which refuse to perform their usual functions to again operate normally; and that it would heal illnesses and correct

organic disorders brought about by daily abuse during months and years. The article would not be an adequate and effective treatment for the diseases and conditions mentioned, and it would not accomplish the results claimed. Further misbranding, Section 502 (f) (1), the directions for use appearing in the labeling of the article, were not adequate for use in the treatment of obesity, paralysis, goiter, and arteriosclerosis: to enable organs of the body which refuse to perform their usual functions to again operate normally; and to heal illnesses and correct disorders brought about by daily abuse during months and years, which were the conditions and symptoms for which the article was prescribed, recommended, and suggested in its labeling.

Abbe Hamon Formula No. 13. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading. The statements represented and suggested that the article would enable the organs of the body which refuse to perform their usual functions to again operate normally, and that the article would heal illnesses and correct organic disorders brought about by daily abuse during months and years. The article would not accomplish the results claimed. Further misbranding, Section 502 (f) (1), the directions for use appearing in the labeling of the article were not adequate for use to enable organs of the body which refuse to perform their usual functions to again operate normally, and to heal illnesses and correct disorders brought about by daily abuse during months and years, which were the conditions and symptoms for which the article was prescribed, recommended, and suggested in its labeling.

DISPOSITION: On May 18, 1953, the defendant filed a motion to dismiss the information, and on June 8, 1953, the court denied such motion. On October 14, 1953, the defendant having entered a plea of nolo contendere, the court imposed a sentence of 3 months in jail which was suspended and placed the defendant on probation for 2 years.

4212. Adulteration and misbranding of C-Tone. U. S. v. 210 Bottles * * *. (F. D. C. No. 35419. Sample No. 57603–L.)

LIBEL FILED: September 4, 1953, District of Columbia.

ALLEGED SHIPMENT: On or about August 17, 1953, by Balanced Foods, Inc., from New York, N. Y.

PRODUCT: 210 bottles of *C-Tone* at Washington, D. C. Analysis showed that 4 tablespoons of the product contained 0.04 milligram of niacin.

LABEL, IN PART: (Bottle) "Rich In Activated Enzymes C-Tone The Natural Vitamin C Tonic * * * Four tablespoons furnish: * * * Natural Niacin . . . 0.08 mg. * * * 8 Fl. Oz. Net."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 0.08 milligram of niacin per 4 tablespoons.

Misbranding, Section 502 (a), the label statement "Four tablespoons furnish: * * * Natural Niacin . . . 0.08 mg." was false and misleading as applied to the article, which contained 0.04 milligram of niacin per 4 tablespoons; and the label statements "Rich In Activated Enzymes" and "Vitamin C Tonic" were false and misleading since such statements represented and suggested that the article was of nutritional and therapeutic value because of enzyme content and that it was effective as a tonic, whereas the article was of no

value because of its enzyme content and was not a tonic. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of high blood pressure, hardening of the arteries, ulcerative colitis, fading strength, nervous exhaustion, failing memory, cerebral rupture, valvular disease of the heart, pulmonary tuberculosis, general weakness, fatigue, headaches, and dizzy spells, and for providing energy and improving digestion, which were the conditions and purposes for which the article was offered in a circular disseminated and sponsored by the distributor, Balanced Foods, Inc., and entitled "Which of These Dread Killers Threaten Your Advancing Years."

DISPOSITION: October 22, 1953. Default decree of condemnation and destruction.

4213. Misbranding of Unitone tablets. U. S. v. 90 Bottles * * *. (F. D. C. No. 35240. Sample No. 20158–L.)

LIBEL FILED: May 19, 1953, District of Minnesota.

ALLEGED SHIPMENT: On or about April 6, 1953, by the Unitone Corp., from New York, N. Y.

PRODUCT: 90 bottles of *Unitone tablets* at St. Paul, Minn.

LABEL, IN PART: (Bottle) "Unitone Brand of B-Amino Complex * * * Vitamins * * * Amino Acids * * * Di and Tri-Valent Minerals * * * Unitone Corporation, Distributors New York, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of deafness, which was the condition for which the article was offered in advertising sponsored by and on behalf of its manufacturer and distributor.

DISPOSITION: October 9, 1953. The shipper of the product having appeared as claimant and filed an answer denying that the product was misbranded, and later having withdrawn its answer and consented to the disposition of the case as a default matter, the court entered a decree providing for the destruction of the product.

4214. Misbranding of Color-Therm device. U. S. v. Fred Gerkey. Motion to dismiss denied. Plea of guilty. Imposition of sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 34853. Sample No. 16460–L.)

INFORMATION FILED: March 31, 1953, District of Kansas, against Fred Gerkey, Mission, Kans.

ALLEGED SHIPMENT: On or about August 2, 1951, from the State of Kansas into the State of Oklahoma.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in that the device failed to bear labeling revealing the conditions for which it was to be used.

DISPOSITION: The defendant filed a motion to dismiss the information on May 6, 1953, and on June 9, 1953, after hearing arguments of counsel, the court overruled the motion. Thereafter, the defendant entered a plea of guilty, and, on October 12, 1953, the court suspended the imposition of sentence and placed the defendant on probation for 1 year.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4215. Adulteration and misbranding of amphetamine sulfate tablets. U. S. v. Leo Henzel (Penn-Lee Products). Plea of nolo contendere. Fine, $200. (F. D. C. No. 24220. Sample Nos. 52302–H, 53635–H.)

INFORMATION FILED: July 8, 1948, Northern District of Illinois, against Leo Henzel, trading as Penn-Lee Products, Chicago, Ill.

ALLEGED SHIPMENT: On or about July 15 and August 31, 1946, from the State of Illinois into the States of Minnesota and Ohio.

LABEL, IN PART: (Bottle) "Amphetamine Sulfate Tablets 10 Mgs. [or "5 Mgs."] per Tablet * * * Penn-Lee Products Chicago Distributors Ill."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), desoxyephedrine hydrochloride had been substituted for amphetamine sulfate.

Misbranding, Section 502 (a), the label statement "Amphetamine Sulfate Tablets" was false and misleading since the article did not consist of amphetamine sulfate tablets but consisted of desoxyephedrine hydrochloride tablets.

DISPOSITION: October 15, 1953. The defendant having entered a plea of nolo contendere, the court fined him $200.

4216. Adulteration of estrogen tablets. U. S. v. Robin Pharmacal Corp. Plea of guilty. Fine, $200. (F. D. C. No. 33783. Sample No. 813–L.)

INFORMATION FILED: May 14, 1953, Southern District of New York, against the Robin Pharmacal Corp., New York, N. Y.

ALLEGED SHIPMENT: Between December 1 and 31, 1950, from the State of New York into the State of Florida.

LABEL, IN PART: (Bottle) "1000 Each tablet contains 1.25 mgm. of estrogens in their naturally occurring water soluble form, expressed as sodium estrone sulfate Robin Pharmacal Co. New York, N. Y. 2339."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet of the article contained less than the declared amount of 1.25 milligrams of estrogens in their naturally occurring water-soluble form expressed as sodium estrone sulfate.

DISPOSITION: October 8, 1953. The defendant having entered a plea of guilty, the court fined it $200.

4217. Adulteration and misbranding of Hep-Vi-Plex. U. S. v. 63 Vials * * *. (F. D. C. No. 34659. Sample No. 66905–L.)

LIBEL FILED: February 12, 1953, Eastern District of Pennsylvania; libel amended March 5, 1953.

ALLEGED SHIPMENT: On or about November 17, 1952, by the Gold Leaf Pharmacal Co., from New Rochelle, N. Y.

PRODUCT: 63 vials of *Hep-Vi-Plex* at Philadelphia, Pa. Analysis showed that the product contained approximately 25 percent of the declared amount of vitamin B_{12} activity per 2 cc.

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*See also Nos. 4209, 4212.

LABEL, IN PART: (Vial) "30 cc Multiple Dose Vial Sterile Solution Hep-Vi-Plex Liver, Iron and Vitamins * * * Each 2 cc represent: Liver Injection (Equivalent in Vitamin B–12 activity to 10 mcg. cyanocobalamin per cc.) . . . 100 mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 100 milligrams of liver injection equivalent in vitamin B_{12} activity to 10 micrograms cyanocobalamin per cubic centimeter in each 2 cubic centimeters.

Misbranding, Section 502 (a) the label statement "Each 2 cc represent: Liver Injection (Equivalent in Vitamin B-12 activity to 10 mcg. cyanocobalamin per cc.) . . . 100 mg." was false and misleading as applied to the article, which contained less than the declared amount of vitamin B_{12} activity.

DISPOSITION: October 8, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4218. Misbranding of shark liver oil capsules. U. S. v. 50 Bottles, etc. (F. D. C. No. 31595. Sample No. 24464–L.)

LIBEL FILED: August 6, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about April 26, 1951, from New York, N. Y.

PRODUCT: 50 50-capsule bottles and 8 250-capsule bottles of *shark liver oil capsules* at Paterson, N. J., in the possession of the Vital Food Service, together with a poster entitled "Eyes Are Rationed" which was on display in the consignee's store.

LABEL, IN PART: (Bottle) "Shark Liver Oil Capsules Each capsule contains refined, blended Shark Liver Oils, standardized to contain not less than 25,000 U. S. P. Units Vitamin A."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement on the above-mentioned poster accompanying the article, namely, "Vitamin A As Vitamin Deficiency May Be the Cause of * * * Sinus Trouble Kidney & Bladder Trouble Poor Resistance to infections Dry Skin Poor Teeth," was false and misleading. The statement represented and suggested that the article, when used as directed, was effective in preventing sinus trouble, kidney and bladder trouble, poor resistance to infection, dry skin, and poor teeth. The article, when used as directed, was not effective for such purposes. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

The libel alleged also that quantities of Special Formula capsules and Vital Veeda capsules were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: Felicia P. Kornreich, trading as Vital Food Service, appeared as claimant and filed an answer on September 28, 1951. On October 18, 1951, the Government filed a motion to strike six separate defenses contained in the answer because some of the alleged defenses were insufficient in law and others were immaterial. The motion was denied by the court on November 26, 1951, with leave to renew the motion at the trial.

On or about March 3, 1952, the claimant filed a motion to dismiss the libel, to vacate the warrant of seizure and monition, and to restore to the claimant

*See also Nos. 4201, 4209, 4211, 4212, 4215, 4217.

the goods seized "on the ground that this court has not acquired jurisdiction over the res." After consideration of the arguments and briefs of counsel, the court, on June 17, 1952, ordered that this motion be dismissed.

On September 21, 1953, the claimant having withdrawn her answer, and without admitting or denying the allegations of the libel, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the products be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4219. Misbranding of hormone hair cream. U. S. v. 6 Dozen Jars, etc. (F. D. C. No. 35251. Sample No. 15009–L.)

LIBEL FILED: May 21, 1953, Northern District of Iowa; libel amended June 17, 1953.

ALLEGED SHIPMENT: On or about January 27 and 30, 1953, by Wanasco Laboratories, from Omaha, Nebr.

PRODUCT: 6 dozen 1-ounce jars and 100 2-ounce jars of *hormone hair cream* at Sioux City, Iowa.

LABEL, IN PART: (Jar) "Hormone Hair Creme For Men and Women A Hyperactive Cream Containing 10,000 I. U. Of Natural Estrogenic Hormone Per Ounce."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the jar label were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for baldness and for preventing baldness, whereas the articles was not an adequate and effective treatment for baldness and for preventing baldness.

DISPOSITION: September 29, 1953. The consignee of the product having filed a claim and answer and later having withdrawn such claim and answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

4220. Misbranding of rowing device. U. S. v. 41 Devices, etc. (F. D. C. No. 35363. Sample No. 69880–L.)

LIBEL FILED: July 24, 1953, District of Colorado.

ALLEGED SHIPMENT: On or about May 6, 1953, by the Kasselberg-Griffith Co., from Chicago, Ill.

PRODUCT: 41 *rowing devices* at Denver, Colo., together with a number of leaflets entitled "Row Your Way to Health." The device consisted of a horizontal rectangular metal frame approximately 3 feet long and approximately 18 inches wide, provided with a movable seat, a footrest, and a movable handle attached to a set of springs by means of a connecting strap.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets accompanying the device were false and misleading. The statements represented and suggested that the device provided an effective method for removing fat deposits from the stomach and hips and for breaking down fatty tissue; and that it provided an adequate and effective treatment for overweight, gaseous troubles, disorders of the bowels, liver, and kidneys, constipation, digestive tract disorders, and skin blemishes, and for enabling the user to regain good health. The device was not an adequate and effective treatment for such conditions and purposes.

DISPOSITION: November 13, 1953. The May Department Stores Co., Denver, Colo., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

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[1] (4202) Motion to dismiss information and to suppress evidence. Contains opinion of the court.

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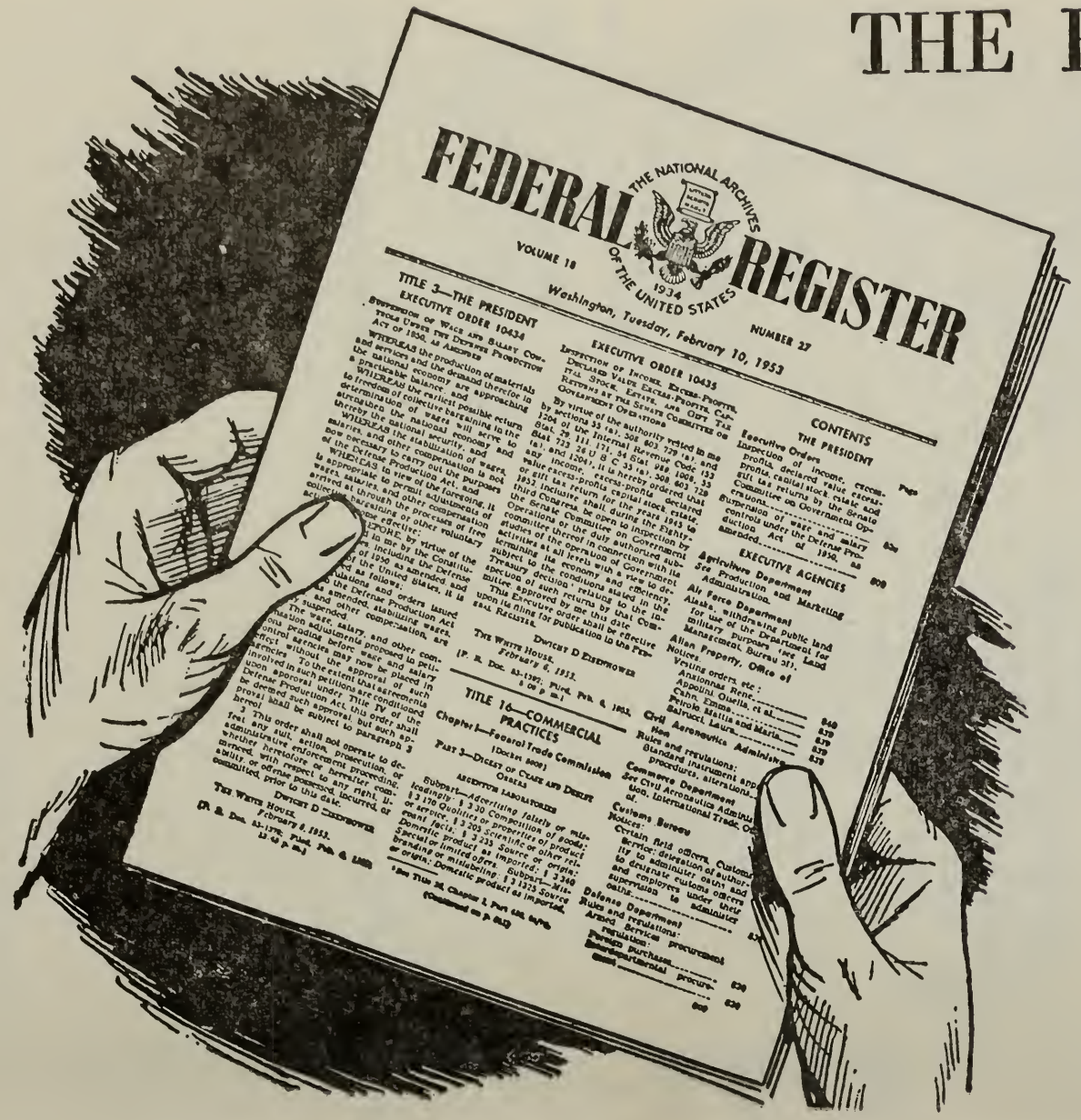

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D. D. N. J., F. D. C. 4221–4240 Issued November 1954

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4221–4240

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *November 4, 1954.*

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*For drug in violation of prescription labeling requirements, see No. 4225; omission of, or unsatisfactory, ingredients statements, No. 4226; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4236.

318014—54——1

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4221. Misbranding of pentobarbital sodium capsules, diethylstilbestrol tablets, and tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfathiazole. U. S. v. Eugene G. Barken. Plea of guilty. Fine, $300. (F. D. C. No. 35179. Sample Nos. 62941–L, 63014–L, 63023–L.)

INFORMATION FILED: October 16, 1953, Eastern District of Missouri, against Eugene G. Barken, pharmacist and manager of Barken's Delmar Loop Pharmacy, University City, Mo.

NATURE OF CHARGE: On or about May 10 and 20, 1953, while a number of *pentobarbital sodium capsules*, *diethylstilbestrol tablets*, and *tablets containing a mixture of sulfamerazine, sulfadiazine, and sulfathiazole* were being held for sale at Barken's Delmar Loop Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: October 30, 1953. The defendant having entered a plea of guilty, the court fined him $300.

4222. Misbranding of methamphetamine hydrochloride tablets, thyroid tablets, and tablets containing a mixture of phenobarbital, acetophenetidin, and acetylsalicylic acid. U. S. v. William F. Cope, Jr. (Standard Drug Co.). Plea of nolo contendere. Fine, $4. (F. D. C. No. 35158. Sample Nos. 36686–L, 36687–L, 57118–L, 70734–L.)

INFORMATION FILED: October 2, 1953, Middle District of Tennessee, against William F. Cope, Jr., trading as the Standard Drug Co., Pulaski, Tenn.

NATURE OF CHARGE: On or about January 19 and 22, February 28, and March 3, 1953, while a number of *methamphetamine hydrochloride tablets*, *thyroid tablets*, and *tablets containing a mixture of phenobarbital, acetophenetidin, and acetylsalicylic acid* were being held for sale at the Standard Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: November 18, 1953. The defendant having entered a plea of nolo contendere, the court fined him $1 on each count for a total fine of $4.

4223. Misbranding of secobarbital sodium capsules and dextro-amphetamine sulfate tablets. U. S. v. Pantaze Drug Co. and Harris B. Renfroe. Pleas of nolo contendere. Fine of $50 against each defendant. (F. D. C. No. 35097. Sample Nos. 47020–L to 47023–L, incl.)

INDICTMENT RETURNED: September 23, 1953, Southern District of Mississippi, against the Pantaze Drug Co., a corporation, Meridian, Miss., and Harris B. Renfroe, secretary-manager of the corporation.

NATURE OF CHARGE: On or about October 13, 1952, and January 20, 1953, while a number of *secobarbital sodium capsules* and *dextro-amphetamine sulfate tablets* were being held for sale at the Pantaze Drug Co., after shipment in interstate commerce, the defendants caused various quantities of the drugs

to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. Such acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: October 2, 1953. The defendants having entered pleas of nolo contendere, the court fined each defendant $50.

4224. Misbranding of sulfathiazole tablets. U. S. v. Elmer E. Reese (Reese Drug Co.). Plea of guilty. Fine, $25. (F. D. C. No. 34821. Sample Nos. 46303–L, 46304–L, 46306–L.)

INFORMATION FILED: October 1, 1953, Middle District of Alabama, against Elmer E. Reese, trading as the Reese Drug Co., Phenix City, Ala.

NATURE OF CHARGE: On or about July 22, 23, and 25, 1952, while a number of *sulfathiazole tablets* were being held for sale at the Reese Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drug to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such act of dispensing was contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: October 1, 1953. The defendant having entered a plea of guilty, the court fined him $25.

4225. Adulteration and misbranding of Cobiplex elixir, Probese capsules, and Sedamar elixir. U. S. v. 10 Bottles, etc. (F. D. C. No. 35303. Sample Nos. 51253–L, 51255–L, 51259–L.)

LIBEL FILED: June 10, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about December 8, 1952, and February 11 and April 9, 1953, by the Mara Laboratories, from Harrison, N. J.

PRODUCT: 10 1-pint bottles of *Cobiplex elixir*, 6 100-capsule bottles of *Probese capsules*, and 5 1-pint bottles of *Sedamar elixir*, at New York, N. Y.

Examination showed that the *Cobiplex elixir* contained 81 percent of the declared amount of vitamin B_1 and 70 percent of the declared amount of vitamin B_2; that the *Probese capsules* contained 40 percent of the declared amount of vitamin A and 85 percent of the declared amount of vitamin C; and that the *Sedamar elixir* contained 14 percent of the declared amount of vitamin B_6.

LABEL, IN PART: (Bottle) "One Pint Elixir Cobiplex," "100 Capsules Probese * * * Caution: To be dispensed only by or on the prescription of a physician," and "One Pint Elixir Sedamar * * * Caution—To be dispensed only by or on the prescription of a physician."

NATURE OF CHARGE: *Cobiplex elixir.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 2 milligrams of vitamin B_1 and 2 milligrams of vitamin B_2 per teaspoonful. Misbranding, Section 502 (a), the label statement "Each Teaspoonful * * * Contains: Vitamin B_1 * * * 2 mg. Vitamin B_2 * * * 2 mg." was false and misleading as applied to the article, which contained less than 2 milligrams of vitamin B_1 and less than 2 milligrams of vitamin B_2 per teaspoonful.

Probese capsules. Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 4000 U. S. P. units of vitamin A and 30 milligrams of vitamin C per capsule.

Misbranding, Section 502 (a), the label statement "Each Capsule Contains: Vitamin A * * * 4000 U. S. P. Units * * * Vitamin C * * * 30 mg." was false and misleading as applied to the article, which contained less than 4000 U. S. P. units of vitamin A and less than 30 milligrams of vitamin C per capsule; and, Section 503 (b) (4), the article was a drug subject to Section 503 (b) (1) (B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Sedamar elixir. Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 1 milligram of vitamin B_6 per teaspoonful. Misbranding, Section 502 (a), the label statement "Each Teaspoonful * * * Contains * * * Vitamin B_6 1 mg." was false and misleading as applied to the article, which contained less than 1 milligram of vitamin B_6 per teaspoonful; and, Section 503 (b) (4), the article was a drug subject to Section 503 (b) (1) (B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: June 29, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4226. Misbranding of herbal preparations. U. S. v. 1 Drum, etc. (F. D. C. No. 34951. Sample Nos. 54977–L to 54985–L, incl.)

LIBEL FILED: April 21, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: Between the approximate dates of October 26, 1951, and October 22, 1952, from Jersey City, N. J.

PRODUCT: 1 80-pound drum of *Formula #8*, 42 6-ounce cartons of *Nervix*, 26 6-ounce cartons of *Gastrix*, 75 6-ounce cartons of *Liverix*, 1 100-pound drum and 1 40-pound drum of *Formula #7*, 60 6-ounce cartons of *Rheumatix*, 1 90-pound drum of *Formula #10*, 10 6-ounce cartons of *Reducerix*, 3 5-ounce cartons of *Urix*, 2 6-ounce cartons of *Anti-Diabetix*, 1 25-pound drum of *Formula #6*, 48 6-ounce cartons of *Chestix*, 1 75-pound drum of *herb mixture for the bath*, and 13 6-ounce cartons of *Bathix* at Chicago, Ill., in the possession of Father Francis' Herbs, together with a number of loose labels relating to the products.

RESULTS OF INVESTIGATION: The articles contained in the cartons had been shipped in bulk, and upon their receipt by the consignee, Father Francis' Herbs, were repackaged into cartons and relabeled as described below. The articles in the drums represented portions of the bulk shipments received by the consignee which had not been at the time of seizure repackaged by the consignee.

Examination of the articles disclosed that they consisted of mixtures of ground plant material. It was assumed for purposes of the action that the articles contained the ingredients which they were represented to contain, namely, (*Formula #8* and *Nervix*) passionflower herb, white willow bark, hawthorne berries, and sweet orange peel; (*Gastrix*) "Johns-wort" herb, knotgrass, woodruff herb, T V senna leaves, juniper berries, buckthorn bark, and peppermint leaves American; (*Liverix*) St.-Johns-wort herb, boldo leaves, buckthorn bark, juniper berries, and knotgrass; (*Formula #7* and *Rheumatix*) knotgrass, horsetail rush, elder flower, ginseng root, buckthorn bark, mistletoe

*See also No. 4239 (veterinary preparation).

leaves and twigs, and coriander seed; (*Formula #10* and *Reducerix*) bladderwrack, goldenrod herb, mistletoe leaves and twigs, sundew herb, buckthorn bark, knotgrass, and star anise seed; (*Urix*) Herniaria glabra, apium petroselinum, orthosyphon stamineus, betula alba, centaurea cyanus, and arbutus uva-ursi (knotweed, parsley, Java tea, white birch, corn flower and uva-ursi); (*Anti-Diabetix*) Hb. Equiseti Arvense, Hb. Hiperici, Fol. Myrtillorum, Fol. Vaccinii Vitis Idaea, Fol. Fragariae, Fol. Calagae Off., Fol. Urticae, Flores Tiliac, Folliculi Phaesoli, Rriz. Craminis, and Rad. Inulae Heleni (horsetail, St.-Johns-wort, myrtle leaves, mountain cranberry leaves, strawberry leaves, galangal leaves, nettle leaves, linden flowers, bean pods, triticum, and inula); (*Formula #6* and *Chestrix*) Verbascum Thapsus, Salvia Officinalis, Pimpinella Anisum, Cetraria Islandica, Symphytum Officinale, and Panax Ginseng (mullein, sage, anise, Iceland moss, comfrey, and ginseng); (*herb mixture for the bath* and *Bathix*) bladder-wrack, rosemary leaves, rosebuds, lemon verbena, orrisroot, thyme, lavender flowers, peppermint, and sage leaves.

LABEL, IN PART: (Drums) "Formula #8 [or "Formula #7" or "Formula #10"] * * * Caution—For Manufacturing Processing or Repacking," "Special Formula #6," and "Herb Mixture For the Bath"; (cartons) "Father Francis' Herbs * * * Nervix [or "Gastrix," "Liverix," "Rheumatix," "Reducerix," "Urix," "Anti-Diabetix," "Chestix," and "Bathix"] (Brand)."

NATURE OF CHARGE: *Formula #8* and *Nervix*. Misbranding, Section 502 (a), the statements on the carton label, namely, (in English and Polish) "For Nerves and Sleeplessness * * * To calm and strengthen the nervous system * * * To bring sleep" were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for nervous disorders and sleeplessness, whereas the article was not an adequate and effective treatment for nervous disorders and sleeplessness.

Gastrix. Misbranding, Section 502 (a), the label designation "Gastrix" and the statement on the carton label (in English and Polish) "For * * * Indigestion" were false and misleading since the article was not effective for gastric disorders and indigestion; Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), its label failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since its labeling failed to warn that, if used as directed in its labeling, namely, "Once or twice daily, pour a cup of boiling water over a tablespoonful of herbs, let draw about an hour, strain, and drink before bedtime, or in the morning," it may cause dependence upon laxatives to move the bowels.

Liverix. Misbranding, Section 502 (a), the label designation "Liverix" and the statement on the carton label "To promote and help regular functions of the Liver and Gall Bladder" were false and misleading since the article was not effective for disorders of the liver and was not effective to promote and help regular functions of the liver and gallbladder; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient. Further misbranding, Section 502 (f) (2), the labeling failed to bear adequate warnings to the effect that, if used frequently or continuously or as directed in the labeling, namely, "2 or 3 times daily, pour a glass of boiling water over 1 tablespoonful of herbs, boil for 3 minutes, let draw about an hour, strain, add

honey if desired and drink before meals," it may cause dependence upon laxatives to move the bowels; and that it should not be used when there was nausea, vomiting, abdominal pain, or other symptom of appendicitis.

Formula #7 and *Rheumatix*. Misbranding, Section 502 (a), the label designation "Rheumatix" and the following statements on the carton label (in English and Polish) "For Rheumatism, Gout, Arthritis" and (in English) "Rheumatism is to be regarded as the name standing for similar troubles such as Neuritis, Sciatica, Lumbago, Muscular Chill, and all muscular Pain" were false and misleading since such statements represented and suggested that the article was an adequate and effective treatment for such disease conditions, when such was not the case.

Formula #10 and *Reducerix*. Misbranding, Section 502 (a), the label designation "Reducerix" and the following statement on the carton label (in English and Polish) "For Obesity and Overweight" were false and misleading since the article was not effective for reducing obesity and overweight; Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), its labeling failed to bear adequate warnings to the effect that, if used frequently or continuously or as directed in the labeling, namely, "Twice daily, pour a glass of boiling water over 1 or 2 tablespoonfuls of herbs, boil for 5 minutes, allow to cool, strain, and drink before breakfast and bedtime," it may cause dependence upon laxatives to move the bowels.

Urix. Misbranding, Section 502 (a), the label designation "Urix" and the statement on the carton label "For Kidneys and Bladder" were false and misleading since the article was not effective for diseases of the kidneys, bladder, and other organs of the urinary tract.

Anti-Diabetix. Misbranding, Section 502 (a), the label designation "Anti-Diabetix" and the statement on the carton label "To promote and help regular functions of the Pancreas (Sugar Diabetes)" were false and misleading since the article was not effective to promote and help regular functions of the pancreas or for diabetes.

Chestix. Misbranding, Section 502 (a), the label designation "Chestix" and the statement on the carton label "For Coughs, Colds, Bronchitis and Lung Troubles" were false and misleading since the article was not effective for diseases of the chest, coughs, colds, bronchitis, and lung troubles.

Herb mixture for the bath and *Bathix*. Misbranding, Section 502 (a), the statement on the carton label "For * * * Strengthening Bath and Douche" was false and misleading since the article was not effective as a strengthening bath and douche; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe duration of administration, in such manner and form, as are necessary for the protection of users since its labeling failed to warn that frequent use as a douche may be harmful.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 9, 1953. Default decree of condemnation and destruction.

4227. Misbranding of Niagara device. U. S. v. 66 Kits, etc. (F. D. C. No. 35344. Sample Nos. 6708–L, 45200–L.)

LIBEL FILED: June 29, 1953, District of Massachusetts.

ALLEGED SHIPMENT: The devices and certain printed matter were shipped by the Niagara Mfg. & Distributing Corp. of Adamsville, Pa., from Lansdowne,

Pa., on or about April 28, 1953, and 10 pages of testimonials were shipped on an unknown date by the Niagara Equipment Distributing Co., from Upper Darby, Pa.

PRODUCT: 66 kits, each kit consisting of 2 articles of device known as the "Niagara All-Purpose Pillow" and the "Niagara Hand Unit," at Boston, Mass., in the possession of Niagara of New England, together with various quantities of accompanying printed matter consisting of a reprint from the February 1953 issue of "The Philadelphia Magazine" entitled "The Story of Niagara" and a reprint from "Science Digest" entitled "'Blood Flow Tells Age'"; a pamphlet headed "Coaches Trainers Athletes . . . Here's how Niagara Deep Massage can help you" and a pamphlet headed "Retail Stores, Restaurants * * * here are coin-operated Niagara Massage-O-Matics"; a folder entitled "Your Personal Masseur Available 24 Hours A Day! Niagara Deep Mechanical Massage"; a reprint from the September 1951 issue of "Hospital Management" magazine headed "In The Field of Physio-Therapy—Niagara Mechanical Equipment Is Unique," a reprint from "Physical Therapy Review" headed "induce complete relaxation with Niagara Cyclo-Therapy," and a reprint from "Modern Hospital" and "Hospital Management" headed "induce complete relaxation with Niagara Cyclo-Therapy"; a salesman's manual headed "Longer Life Is Yours Today"; and 10 pages of testimonials (these testimonials were inserted in the salesman's manual).

Examination showed that the devices were vibrators. The hand unit was so designed as to adapt it to be held in the hand while being applied to any part of the body, and the all-purpose pillow was designed for sitting, leaning, or resting the feet upon.

NATURE OF CHARGE: Misbranding, Section 502 (a), the accompanying labeling of the devices, namely, the above-mentioned reprints, pamphlets, folders, and salesman's manual, contained statements which were false and misleading. The statements represented and suggested that the devices would insure good circulation, enabling the user to regain and maintain it, effect rejuvenation, correct circulatory ailments, reduce and prevent injuries, effect increased rapidity of healing injuries, pulled tendons, and other muscle and bone injuries, reduce absenteeism, keep the most inactive person in good condition, and remedy sore and aching muscles, sore legs, and stiff joints; that they would effectively treat sleeplessness, hypertension, circulatory deficiencies, and cartilaginous and bony overgrowths; that they would heal broken ankles, effect increase in weight of thin girls, help nature keep the human body functioning properly, and trim one's figure; that they would effectively treat dislocations, injured elbows, knees, wrists, ankles, etc.; and that they would prevent muscular atrophy after injury, speed the healing of fractures and spinal injuries, and assist the heart. The devices would not effect the results or fulfill the promises of benefit stated and implied. The devices were misbranded in the above respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the accompanying labeling of the devices, namely, the 10 pages of testimonials inserted in the salesman's manual, contained statements which were false and misleading. The statements represented and suggested that the devices constituted an effective treatment for multiple sclerosis, kidney disorders, fibrous swelling or infiltration in the interior of the body, accumulation of fibrous, cartilaginous, and body overgrowth of joint, chronic degenerative conditions, including arthritis and diabetes, sinus condition, muscular contractures, tumors, varicosities and

eruptions, and hemiplegia; and that the devices would help humanity restore itself to normal health, improve respiratory processes and functions, stimulate secretion, improve muscular and general metabolism, stimulate the excretory organs, and assist elimination. The devices would not effect the results nor fulfill the promises of benefit stated and implied. The devices were misbranded in this respect while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for effective treatment of poor circulation, circulatory ailments, sore, aching joints, sagging chin, etc., insomnia, bruises, sprains, fractures, and many other bone and muscle ailments, sagging muscles, varicose veins, arthritis, gangrene, paralysis resulting from polio, bursitis, prostate gland trouble, pain and paralysis of arm and leg after stroke, constipation, and broken ankles; and for preventing malfunctioning of the heart, lungs, liver, and intestines, enabling all to keep in better physical condition, adding years to one's life, and keeping one young without the usual pains and aches, which are the purposes for which the articles were offered in an advertisement in a Boston newspaper disseminated and sponsored by the distributor, Niagara of New England, and orally by a representative of the consignee. The devices were misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: July 21, 1953. Niagara of New England, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the printed matter which accompanied the devices be destroyed and that the devices be released to the claimant.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4228. Adulteration of agaric root (peelings). U. S. v. 3 Bags * * *. (F. D. C. No. 35406. Sample No. 49983–L.)

LIBEL FILED: August 28, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about October 27, 1952, from Missoula, Mont.

PRODUCT: *Agaric root* (peelings). 3 bags, each containing 272 pounds, of the product at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects.

DISPOSITION: September 21, 1953. Default decree of condemnation and destruction.

4229. Adulteration of Private Formula No. 21. U. S. v. 72 Bottles * * *. (F. D. C. No. 35443. Sample No. 62101–L.)

LIBEL FILED: July 29, 1953, Southern District of Iowa.

ALLEGED SHIPMENT: On or about June 10, 1953, from Peoria, Ill.

PRODUCT: 72 6-ounce bottles of *Private Formula No. 21* at Davenport, Iowa.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of mold. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 18, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4230. Action to enjoin and restrain interstate shipment of drugs intended for injection. U. S. v. Milton A. Calesnick (Addison Laboratories). Temporary restraining order entered; order subsequently vacated and dismissed. (Inj. No. 253.)

COMPLAINT FILED: August 14, 1952, Eastern District of Pennsylvania, against Milton A. Calesnick, trading as Addison Laboratories, Philadelphia, Pa.

NATURE OF CHARGE: The complaint alleged that the defendant was engaged in manufacturing and distributing and shipping in interstate commerce various drugs intended for injection into the human body which were adulterated and misbranded as follows:

(a) Adulteration, Section 501 (b), a number of the drugs purported to be and were represented as drugs, the names of which are recognized in official compendia, namely, the United States Pharmacopeia and the National Formulary, and the strength of the drugs differed from, and their quality and purity fell below, the standards set forth in such compendia; Section 501 (c), in the case of a number of the drugs, their strength differed from, and their purity and quality fell below, that which they purported and were represented to possess; and, Section 501 (d) (2), in the case of a number of the drugs, certain substances had been substituted for the drugs.

(b) Misbranding, Section 502 (a), the labeling of a number of the drugs bore false and misleading statements with respect to the nature and quantity of the ingredients contained in the drugs.

The complaint alleged further that the adulterated and misbranded condition of the drugs resulted from deficiencies in the ingredients of the drugs, the presence of ingredients in amounts in excess of those declared on the labels or required by the standards set forth in the official compendia, the substitution of other drugs for the drugs involved, and the presence of viable micro-organisms evidencing an unsterile product. For example, examination of samples from interstate shipments made by the defendant of certain articles of drug for injection, to wit, liver-folic acid-B_{12}, aminophylline, sodium salicylate and iodide with colchicine, and Lynntestro, disclosed that the liver-folic acid-B_{12} contained approximately 7 percent of the declared amount of vitamin B_{12}; that the aminophylline contained theophylline in excess of the amount permitted by the United States Pharmacopeia; that a number of ampuls of the sodium salicylate and iodide with colchicine did not contain the declared ingredients in that aminophylline had been substituted for such ingredients; and that the Lynntestro was not sterile since it contained viable micro-organisms.

The complaint further alleged that the defendant was well aware that his activities were violative of the Act. Inspections were made of the defendant's plant at Philadelphia, Pa., by inspectors of the Food and Drug Administration on May 18 and August 2, 1950, April 19 and November 26, 1951, and June 9, 20, and 23, and July 22, 1952, at which times the defendant was informed of the lack of analytical and sterility controls in the manufacture of drugs and of the confusion and disorder existing in the plant, which would result in errors of composition and labeling, and was warned that such conditions also would result in the drugs being adulterated and misbranded as aforesaid.

*See also No. 4225.

The complaint alleged further that despite the warnings conveyed to the defendant by the plant inspections, the defendant continued to introduce and deliver for introduction into interstate commerce drugs which were adulterated and misbranded as described above.

DISPOSITION: On August 14, 1952, the court entered a temporary restraining order, under which the defendant was temporarily restrained and enjoined from directly or indirectly introducing, or delivering for introduction into interstate commerce, drugs adulterated and misbranded in the manner complained of. On August 20, 1952, pursuant to a stipulation between the Government and the defendant, the court entered an order continuing the temporary restraining order in effect.

On December 21, 1953, upon consideration of a motion from the defendant showing that the drugs being shipped by the defendant were in compliance with the law in that such drugs were being manufactured under proper analytical and sterility controls, the court entered an order vacating the temporary restraining order and dismissing the complaint.

4231. Adulteration and misbranding of Visnico tablets. U. S. v. 110 Bottles, etc. (F. D. C. No. 35410. Sample No. 22865–L.)

LIBEL FILED: August 27, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about May 28, 1953, by the Bonded Laboratories, from Brooklyn, N. Y.

PRODUCT: 110 1,000-tablet bottles and 552 100-tablet bottles of *Visnico tablets* at East Orange, N. J.

LABEL, IN PART: (Bottle) "Pulvoids No. 500 Visnico (with Phenobarbital) Each Pulvoid Contains: * * * Potassium Nitrate 2 grains Sodium Nitrite 1 grain."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 grains of potassium nitrate and 1 grain of sodium nitrite per tablet.

Misbranding, Section 502 (a), the label statements "Potassium Nitrate 2 grains" and "Sodium Nitrite 1 grain" were false and misleading since the article contained less than the declared amounts of such ingredients.

DISPOSITION: October 1, 1953. Default decree of condemnation and destruction.

4232. Adulteration and misbranding of lubricating jelly. U. S. v. 95 Cartoned Tubes * * *. (F. D. C. No. 35448. Sample No. 42752–L.)

LIBEL FILED: August 6, 1953, Northern District of California.

ALLEGED SHIPMENT: On or about May 6, 1953, by the Tablex Co., from New York, N. Y.

PRODUCT: 95 cartoned tubes of lubricating jelly at San Francisco, Calif.

LABEL, IN PART: "A non-greasy water soluble surgical lubricant lens lubricating jelly sterile."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity of the article fell below that which it purported and was represented to possess since it purported to be sterile when, in fact, it was not sterile.

Misbranding, Section 502 (a), the label statement "sterile" was false and misleading as applied to an article which was not sterile.

DISPOSITION: September 28, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4233. Misbranding of vitamin and mineral tablets. U. S. v. 12 Bottles, etc. (F. D. C. No. 34884. Sample Nos. 40638–L to 40648–L, incl.)

LIBEL FILED: March 16, 1953, Western District of Washington.

ALLEGED SHIPMENT: On various dates, on and after October 14, 1952, by J. M. Sleighter, from Salem, Oreg.

PRODUCT: 12 bottles of the $12.00-size, 41 bottles of the $5.00-size, and 41 cartons of the sample size of Elemin mineral tablets; 3 bottles of the $12.00-size and 25 bottles of the $5.00-size of multiple vitamin tablets; 6 cartons of the $9.00-size and 5 cartons of the $30.00-size of an article designated as "Royal Formula" and containing a number of Elemin mineral tablets and a number of multiple vitamin tablets; and 7 cartons of the $21.00-size and 4 cartons of the $12.00-size of an article designated as "Supreme Formula," and containing a number of Elemin mineral tablets and a number of multiple vitamin tablets, at Seattle, Wash., together with a number of accompanying leaflets, circulars, and booklets entitled "Elemin Mineral Tablets," "Elemin Mineral Tablets and Royal Formula Multiple Vitamins," "Elemin Mineral Tablets and Supreme Formula Multiple Vitamins," "Mineral Chart," "It's Later Than You Think Watch Your Diet," "Health Facts You Should Know! Elemin Mineral tablets * * *," "Health Facts You Should Know. Compiled by A. Goeke," "Facts You Should Know," "Did You Know That 999 out of every 1000 people lack the proper nutrition," "Young Middle Aged and Elderly People!" "The Following is a Reprint of a Published Article, For Informative and educational purposes only, *not to be used in the sale of any product*," "Soil A Foundation of Health," and "Modern Miracle Men," all of which contained statements relating to the articles.

RESULTS OF INVESTIGATION: Some of the leaflets, circulars, and booklets mentioned above were shipped by J. M. Sleighter from Salem, Oreg., on various dates during 1951, 1952, and 1953, and some of the material was printed locally on the order of Loran S. Stone of Seattle, Wash., the consignee of the products, or obtained by him from a supplier in Milwaukee, Wis.

LABEL, IN PART: (Elemin mineral tablets) "As a Source of the Minerals Iron and Iodine Contains: Iodine and Iron as naturally present in dehydrated kelp, iron gluconate and a sedimentary mineral deposit, with excipients * * * Four Tablets Per Day Will Provide: Iodine–Not less than 0.2 milligrams 200% minimum daily adult requirements. Iron–Not less than 30.0 milligrams 300% minimum daily adult requirements. * * * The ingredients in this product are from dehydrated kelp, iron gluconate and sedimentary mineral deposits"; ($12.00-size and $5.00-size) "Manufactured for Morgan & Bush, Inc. 415 Brower Bldg., Bakersfield, Calif. Distributed Exclusively by–G & J Distributors 1945 Grove St., Berkeley 4, California"; (sample size) "Distributed by G & J Distributors 1945 Grove St., Berkeley 4, Calif."

(G & J Formula No. 701 [or 601] multiple vitamins) "Each 2 Tablets Will Supply: Vitamin A * * * . . . 5,000 U. S. P. Units Vitamin D * * * . . .

*See also Nos. 4225–4227, 4230–4232.

1,000 U. S. P. Units Vitamin B_1 * * * . . . 3.0 Mg. Vitamin B_2 * * * . . . 2.0 Mg. Vitamin B_6 * * * . . . 1.0 Mg. Vitamin B_{12} . . . 1.0 Mcg. Vitamin C * * * . . . 50.0 Mg. Vitamin E * * * . . . 3.0 Mg. Niacinamide . . . 20.0 Mg. Calcium Pantothenate . . . 5.0 Mg. Concentrated Beef Liver Extract . . . 65.0 Mg. Mfd. for G & J Distributors Dist. by 1945 Grove Street Berkeley 4, California * * * G & J Multiple Vitamin Tablets are formulated as a convenient source for increasing intake of listed ingredients."

(Royal Formula) "Elemin * * * Mineral Tablets As a Source of the Minerals Iron and Iodine Contains: Iodine and Iron as naturally present in dehydrated kelp, iron gluconate and a sedimentary mineral deposit with excipients * * * G & J Multiple Vitamins * * * 2 Tablets Daily Will Supply: MDR Vitamin A * * * 10,000 USP Units 250% Vitamin D * * * 1,000 USP Units 250% Vitamin B_1 * * * 3.0 Mg. 300% Vitamin B_2 * * * 2.0 Mg. 100% Vitamin B_6 * * * 1.0 Mg. Vitamin B_{12} * * * 1.0 Mcg. Vitamin C * * * 50.0 Mg. 166% Vitamin E * * * 3.0 Mg. Niacinamide 20.0 Mg. Calcium Pantothenate 5.0 Mg. Choline * * * 10.0 Mg. Inositol 10.0 Mg. Chlorophyll 1.0 Mg. Para Aminobenzoic Acid 5.0 Mg. Rutin 1.0 Mg. Conc. Beef Liver Extract 65.0 Mg. Plus other B-Complex factors from natural sources, (Yeast and Liver) With excipients and Binders. * * * Distributed by G & J Distributors 1945 Grove St.—Berkeley 4, Calif."

(Supreme Formula) "Elemin * * * Mineral Tablets As a Source of the Minerals Iron and Iodine Contains: Iodine and Iron as naturally present in dehydrated kelp, iron gluconate and a sedimentary mineral deposit with excipients, and artificial color added to coating. 4 Tablets per day (suggested daily intake) will provide: Iodine–not less than 0.2 Mg. 200% minimum daily adult requirement. Iron–not less than 30.0 Mg. 300% minimum daily adult requirement. Distributed by G & J Distributors 1945 Grove St.—Berkeley 4, Calif. 2 Tablets daily will supply: MDR Vitamin A . . . 25,000 USP Units 625% Vitamin D . . . 1200 USP Units 200% Vitamin B_1 . . . 8.0 Mg. 800% Vitamin B_2 . . . 5.0 Mg. 250% Vitamin B_6 . . . 2.0 Mg. Vitamin B_{12} . . . 1.0 Mcg. Vitamin C . . . 150.0 Mg. 500% Vitamin E . . . 10.0 Mg. Niacin . . . 10.0 Mg. Niacinamide . . . 40.0 Mg. Calcium Pantothenate . . . 10.0 Mg. Inositol 10.0 Mg. Choline . . . 10.0 Mg. Para Aminobenzoic Acid . . . 10.0 Mg. Rutin . . . 1.0 Mg. Folic Acid . . . 1.0 Mg. Chlorophyll . . . 1.0 Mg. Alfalfa Concentrate, Excipients, Binders, and Artificial Color in Coating."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the articles, namely, the above-mentioned leaflets, circulars, and booklets, was false and misleading since the representations and suggestions made in such labeling were contrary to fact. The labeling when taken as a whole, as well as in specific statements, and when read in the light of the setting in which such labeling was intended to be read, conveyed to the public a meaning which represented and suggested—

(a) That malnutrition is the only disease; that the causes of fatal diseases are not germs but food consumed; that Americans occupy a low position in the national health scale; that 99% of Americans are suffering from mineral deficiencies resulting in sickness, suffering, and the shortening of life; that complete health requires, in addition to a wide variety of natural foods, supplementary vitamins and minerals; that a balanced and fully nourishing diet must contain boron, zinc, and cobalt; that millions of Americans are suffering from rheumatism, heart disease, arthritis, and other diseases resulting from faulty nutrition; that vast areas of soil do not contain needed minerals, and,

as a consequence, people and also animals subsisting on crops grown on such soil are starving, weak, and increasingly suffering from degenerative diseases, including high blood pressure, heart trouble, tumor, cancer, rheumatism, and many other diseases; and that such consequences can be prevented by the ingestion of Elemin tablets and G & J multiple vitamins tablets;

(b) That vitamin and mineral supplementation of the ordinary diet, such as the vitamins and minerals supplied by Elemin tablets and G & J multiple vitamins tablets is needed to prevent mental disease, cancer in newborn infants, and poliomyelitis;

(c) That Elemin tablets and G & J multiple vitamins tablets constitute an effective remedy for varicose veins;

(d) That sodium is an alkalizer and a digestive, it enables the body to take up iron, and it prevents catarrh and hardening processes; its lack causes iron insufficiency, indigestion, and old age deposits; sulfur purifies and tones up the system, makes hair glossy, and promotes bile secretion; its lack causes piling up of impurities and failure of the liver to function normally; potassium heals, balances, activates, relieves pain, helps prevent constipation, stimulates the liver, and renders tissues elastic; its lack causes constipation, pimples, failure of sores to heal, and liver disorders; magnesium is refreshing, promotes sleep, gives control of the nervous system and recuperation, and aids the complexion; its lack causes restlessness, excess acidity, and nervous conditions; iodine regulates the glands and protects the brain from body toxins; chlorine keeps joints and tendons supple, helps prevent pyorrhea, autointoxication, and excess fat; its lack causes undue accumulation of waste matter; fluorine acts as an antiinfective agent and helps prevent bone disease; its lack causes bad eyesight, pyorrhea, and susceptibility to infection; silicon makes tissues lithe and supple, the hair glossy, and the eyesight and complexion bright; its lack causes baldness, gray hair, bad complexion, and skin trouble; manganese promotes proper nutrition and fertility and activates other minerals; its lack causes sterility, lameness, and poor joints; and that such minerals supplied by Elemin tablets would accomplish the results stated and implied; would correct the conditions and deficiencies enumerated; and would supply such minerals to prevent such conditions and deficiencies from occurring;

(e) That a clay, described in the labeling as "sedimentary mineral deposit" occurring near Panaca, Nev., used as an ingredient of Elemin tablets contributed significantly to the diet of the user.

The above-mentioned articles were misbranded while held for sale after shipment in interstate commerce. The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 18, 1953. Default decree of condemnation and destruction.

4234. Misbranding of artificial mineral water. U. S. v. 366 Cases, etc. (F. D. C. No. 34961. Sample No. 57047–L.)

LIBEL FILED: April 28, 1953, Northern District of Ohio; amended libel filed May 26, 1953.

ALLEGED SHIPMENT: On or about April 28, 1953, by Nuvi-T-Min, Inc., from Gordonville, Pa.

PRODUCT: 366 cases, each containing 2 1-gallon bottles, of *artificial mineral water* at Toledo, Ohio, together with a number of accompanying pamphlets entitled "Functions of Minerals in Nutrition."

Analyses showed that the article consisted of approximately 99.5 percent water and 0.5 percent dissolved mineral matter, nearly all of which was sodium sulfate, and that there were but inconsequential traces of other minerals.

LABEL, IN PART: (Bottle) "Nuvi-T-Min, Inc. Artificial Mineral Water."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned accompanying pamphlets were false and misleading since the article was not effective for the purposes stated and implied and would not fulfill the promises of benefit made for it. The statements represented and suggested that the sulfur in the article would favorably affect the liver, blood vessels, nerves, complexion, hair, nails, skin, and cornea of the eye; that it would regulate innervation, purify and tone the system, and warm the skin; that it was necessary to metabolism; and that it contributed to the production of taurocholic acid in bile, thioneine in blood corpuscles, and glutathione in all the cells of the body; that iron in the article would make red blood, rosy cheeks, and clear complexion; that it would supply energy and vitality; that it would absorb and aid in transport of oxygen; that it would nourish tissues from the blood stream; and that it would prevent anemia; that the phosphorus in the article would favorably affect the bones and brain; that it would strengthen mental powers; that it would improve nutrition of nerve tissues and hair tissues; that it would favorably affect life and growth; that it would aid in the growth of hair; that it would contribute in a significant manner to the formation of bones, teeth, nerves, and the cells of the brain; that it would contribute to the prevention of rickets and other bone diseases; that it would favorably affect the metabolism of carbohydrates and fats; that it would produce alkalinity; that it would stimulate the liver; that it would favorably affect growth; that it would have a regulating effect upon the hair and on muscle contractions; and that it would be of vital importance to the red blood cells; that the calcium in the article would build bones, muscles, and teeth; that it would counteract acids, aid vitality, soothe the nerves, and decrease nervousness; that it would stimulate courage; that it would favorably affect functioning of the muscles and the clotting of blood, thus assisting in preventing hemorrhaging; and that it would affect normal beating of the heart; that the sodium in the preparation would check fermentation; that it would prevent clotting of blood; that it would stimulate the spleen; that it would regulate heat in body fluids; that it would excite the stomach and bowels to greater action; that it would neutralize acids; that it would help to maintain osmotic equilibrium in the tissues and in keeping proteins of the cells in solution and in proper degree of dispersion for normal functioning; and that it would protect body tissues against excessive loss of water; that the magnesium in the article would promote cell building in nerve matter; that it would promote excretions; that it would aid in preventing constipation; that it would be effective for steadying the nerves by depressing nervous irritability; that it would help to overcome brain fatigue; that it would stimulate the liver and reduce temper; that it would favorably influence all living cells; that it was of importance in the digestion of carbohydrates (starches and sugars) and fats; that it would favorably affect muscular action and yeast fermentation in the body; and that it would be effective in blood building and in the maintenance of healthy teeth; that the silicon in the article would act as a protective to skin and body; that it would increase hair growth; that it would aid in regulating enamel on the teeth; that it would favorably affect growth of teeth and nails; that it would stimulate the brain; that it would give grace to the body and sparkle to the eyes; and that it would promote beauty; that the

chlorine in the article would help to expel wastes; that it would assist in cleansing and purifying the system; that it would exercise favorable influence upon metabolism and help to maintain osmotic pressure in blood and tissues; that it would aid digestion; that it would aid in the regulation and stimulation of muscular action; that it would activate body enzymes; and that it would contribute to normal gastric secretion and to the maintenance of normal heart action; that the fluorine in the article would be effective in building strength into bone structures; that it would act strongly on the spleen; that it would help to protect the consumer from germs and infections; and that it would aid in preserving youthfulness in youth and old age; that the cobalt in the article would effect normal growth, normal appetite, and normal skin; that it would assist in increasing the red blood corpuscles; and that it would be effective to prevent scaly skin and muscular degeneration; that the manganese in the article would favorably affect nerve and brain cells; that it would increase the ability to read small print and to notice objects at a greater distance; that it would strengthen memory; that it would quicken coordination of thought and action; that it would contribute effectively to reproduction, growth, and normal functioning of the human body; that it would give stability to the bone structure of the body; that it would control the body's ability to utilize the vitamin B complex; and that it would contribute to the formation of the color pigment in hair, thus preventing hair from graying; that zinc in the article would be effective in increasing the bodily resistance to temperatures; that it would favorably affect tissue respiration and the proper utilization of vitamin B_1 by the human system; and that it would prevent retardation of intestinal absorption and decrease in growth rate; that the copper in the article would be effective in preventing the graying of hair and that it would aid tissue respiration.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: July 16, 1953. Nuvi-T-Min, Inc., and W. R. Devlin, Gordonville, Pa., the owners of the product, having appeared as claimants, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4235. Misbranding of Nemow tablets. U. S. v. 15 Display Cartons * * *. (F. D. C. No. 35359. Sample No. 50980–L.)

LIBEL FILED: July 17, 1953, District of New Jersey.

ALLEGED SHIPMENT: On or about November 6, 1952, by Nemow Co., Inc., from New York, N. Y., and on or about March 5, 1953, by the Commerce Drug Co., from Brooklyn, N. Y.

PRODUCT: 15 display cartons, each containing 12 boxes, of *Nemow tablets* at Newark, N. J.

LABEL, IN PART: (Display carton) "Nemow For Relief of Functional Periodic Pain"; (box) "Nemow 6 Tablets Active Ingredients, Acetphenetidin 2 Grains Per Tablet, Phenyl-Propanol-Amine Hydrochloride (Propadrine Hydrochloride), Aspirin For Relief of Functional Menstrual Pain."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement appearing in the labeling of the article, namely, (on leaflet enclosed in each box) "Nemow Tablets * * * do away with much of the depression and 'blue feeling' often experienced during or before the menstrual period," was false and misleading

since the article would not effect the result and would not fulfill the promise of benefit stated and implied.

DISPOSITION: September 21, 1953. Default decree of condemnation and destruction.

4236. **Misbranding of 3 Roses Hair Gror. U. S. v. 222 Jars * * *.** (F. D. C. No. 35306. Sample No. 55145–L.)

LIBEL FILED: June 9, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about April 3 and May 6, 1953, from Tampa, Fla. This was a return shipment.

PRODUCT: 222 jars of *3 Roses Hair Gror* at Milwaukee, Wis. Analysis showed that the product was petrolatum, with perfume and certified coal-tar colors added. The product was contained in glass jars, each containing approximately 13 ounces by weight.

LABEL, IN PART: (Jar) "Don't Starve Your Hair Keep it growing! Contents 4 Ozs. or Over Use 3 Roses Hair Gror Will Improve Your Hair Instantly."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "3 Roses Hair Gror" and the label statements "Don't Starve Your Hair Keep it growing!" and "Will Improve Your Hair Instantly" were false and misleading. These statements represented and suggested that the article would grow hair, whereas the article would not grow hair.

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents since the label statement "Contents 4 Ozs. or Over" was inaccurate.

DISPOSITION: November 18, 1953. Default decree of condemnation and destruction.

4237. **Misbranding of Magnetic Ray belt. U. S. v. 1 Device, etc.** (F. D. C. No. 35324. Sample No. 67254–L.)

LIBEL FILED: June 24, 1953, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about May 25, 1953, by Dr. Frank B. Moran, from Coppell, Tex.

PRODUCT: 1 device known as *Magnetic Ray belt* and its accessory (consisting of a coil of wire attached to a socket containing a flashlight bulb) at Purvis, Miss., together with a number of pamphlets entitled "Directions For Taking Magnetic Ray Treatments" and "Magnetic Ray Treatment" and a letter dated May 24, 1953, from "Magnetic Ray Company, Frank B. Moran, M. D."

The device was a belt consisting of a coil of wire intended for connection to a source of electric current. Accompanying the belt, but not attached to it, was the accessory consisting of a coil of wire attached to a socket containing a flashlight bulb which glowed when the secondary coil was brought near the belt, if the belt was in operation. By means of this accessory the user was able to determine whether an electric current was passing through the belt.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned pamphlets and letter accompanying the device and its accessory were false and misleading. The statements represented and suggested that the device constituted a powerful factor in restoring and preserving health, an effective weapon to fight disease, a source of health-giving rays, and an effective modality in the prevention and relief of human ills, the treatment and prevention of disease, and in effecting a healthful body and mind at ease;

that the device would provide an adequate and effective remedy for disease, bodily weakness, and defects, autotoxemia, poisoning from putrefactive changes occurring in the contents of sluggish intestines, infected teeth, tonsils, sinuses, and other parts of the body, colds, influenza, pneumonia, etc., and worry; that it would equalize the circulation of the blood relieving congestion; that it would relieve pain and other distressing physical sensations; that it would effect relaxation and promote sleep; that it would stimulate normal functioning of the glands and other organs of the body; that it would overcome fatigue and "that tired feeling"; that it would raise the vital tone of the system and increase physical and mental efficiency; that it would exercise revitalizing influence upon the sexual or procreative glands; that it would clear the complexion; and that it would cause absorption of abnormal growths and deposits such as goiter, tumors, and blood clots resulting from hemorrhages due to high blood pressure; for asthma, arthritis, Bright's disease, diabetes, coronary thrombosis, high blood pressure, paralysis, enlarged joints, stiff joints, bronchial cough, bladder trouble, backache, deafness, constipation, eczema, headaches, indigestion, neuralgia, cold extremities, insomnia, lumbago, painful menstruation, nervous breakdown, obesity, rheumatism, sciatica, fibroid tumors, uterine hemorrhages, varicose veins and ulcers, sinus trouble, many difficult chronic conditions, hay fever, catarrhal conditions of the nasal passages, disorders of the prostate gland, hemorrhoids and other affections of the pelvic organs, pain and swelling of the feet, nervous irritability, organic heart trouble, and low blood pressure; and that the device would improve the circulation and elimination and develop a high state of vitality and a greater resistance to every sort of disease. The device would not accomplish such results; it would not be effective for such purposes; and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: September 21, 1953. Default decree of condemnation and destruction. On September 23, 1953, the decree was amended to provide for the delivery of the device to the Food and Drug Administration.

4238. Misbranding of Pedasine device, Electro-Pulse device, and Vita Motor device. U. S. v. 11 cartoned Devices, etc. (F. D. C. No. 34675. Sample Nos. 33756–L to 33758–L, incl.)

LIBEL FILED: February 25, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: The *Pedasine devices* were shipped by R. A. Fischer & Co., from Glendale, Calif., on or about November 9, 1951, and November 18, 1952; the *Electro-Pulse devices* were shipped by Ray Strahan Mfg., from Los Angeles, Calif., on or about November 7, 1952; and the *Vita Motor devices* were shipped by the Vita-Motor Co., from San Diego, Calif., on or about March 30, 1951, and November 19, 1952.

PRODUCT: 11 cartoned *Pedasine devices* with accompanying labeling furnished by the shipper, consisting of leaflets entitled "The Famous Fischer Pedasine Beneficial for Blood Pressure Cases," "The New Pedasine," and "Operating Instructions for the Fischer Pedasine"; reprints entitled "Blood Pressure" and "Diastolic Hypertension"; and catalogs entitled "The Fischer (Glendale) Line of Electro-Medical Apparatus and Accessories."

6 cartoned *Electro-Pulse devices* with accompanying labeling furnished by the shipper, consisting of leaflets entitled "Presenting The Electro-Pulse."

2 *Vita Motor devices* with accompanying labeling furnished by the shipper, consisting of leaflets entitled "The Physiology of Tissue Surge Percussion,"

together with additional accompanying labeling which had been printed upon instructions of the consignee, the Stanley Physical Therapy Equipment & Supply Co., and which consisted of copies of a catalog entitled "The Practical Physical Therapist, Volume 7, January 1951," and containing statements relating to each of the devices.

The devices and their accompanying labeling were, at the time of seizure, in the possession of the Stanley Physical Therapy Equipment & Supply Co., at Chicago, Ill.

Examination showed that the *Pedasine device* consisted of an oblong case with metallic foot plates built into it and that, when plugged into an electric outlet, the device would produce a sinusoidal current; that the *Electro-Pulse device* was a heating and pulsating device; and that the *Vita Motor device* was a vibrator.

LABEL, IN PART: "Pedasine * * * R. A. Fischer & Co. Glendale 3 Calif"; "Electro-Pulse Manufactured by Enn-Tee Electric Company * * * North Hollywood, Calif."; and "The Vita Motor Percusser Spynengine Type D."

NATURE OF CHARGE: *Pedasine device.* Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for high blood pressure, paralysis, arthritis, fallen arches, poor circulation, constipation, flabby skeletal muscles, flabby visceral muscles, and "many other physical conditions." The device would not provide an adequate and effective treatment for such conditions.

Electro-Pulse device. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for rectal and vaginal disorders, chronic constipation, cryptitis, nocturia, prostate hypertrophy, proctitis, prostatitis, acute or chronic endometritis, cervicitis, vaginitis, gastrointestinal neuroses, mucus colitis, hemorrhoids, neurocirculatory disturbances, cephalalgias, and neuropsychiatric cases. The device would not provide an adequate and effective treatment for such conditions.

Vita Motor device. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device were false and misleading. The statements represented and suggested that the device would provide an adequate and effective treatment for amenorrhea, angina pectoris, aneurism of the aorta, pain in the appendix, asthenopia, bronchial asthma, cardiac asthma, atelectasis, bed wetting, catarrh of the bile ducts, pain in the bladder, high blood pressure, congestion of splanchnic blood vessels, congestion of the brain, congestion of the bronchial mucosa, bronchitis, spasmodic bronchostenosis, cardiospasm, chilblains, chlorosis, cold in the head, spasmodic intestinal colic, constipation, coryza, cough, diabetes mellitus, nervous diarrhea, drowning, pain of duodenal ulcers, dysmenorrhea, nervous dyspepsia, dyspena from heart failure, congestion of the ear, deafness (middle ear), cardiac and renal edema, electrocution, emphysema, enteroptosis, enterospasm, enuresis, epistaxis, amblyopia, asthenopia, congestion of the eyes, nervous affections of the eyes, inflammation of the gallbladder, gallstone, goiter, hay fever, arrhythmia, heart insufficiency, mitral stenosis, myocarditis, pain in the heart, palpitation of the heart, tachycardia, valvular insufficiency of the heart, weakness of the heart, hemoptysis, hemorrhoids, hepatic colic, hepatic congestion, hiccough, hot flashes at menopause, hyperthyroidism, infantile paralysis, intesti nal tympanites, pain in the intestines, prolapsed intestines, catarrhal jaundice.

inflammation of the kidneys, pain in the kidneys, prolapsed kidneys, cirrhosis of the liver, pain in the liver, locomotor ataxia, lumbago, hemorrhage of the lungs, excessive menstruation, painful menstruation, suppression of menstruation, nephritis, neurasthenia, nosebleed, congestion of the ovaries, pertussis, piles, heart weakness in pneumonia, poliomyelitis, pain in the prostate gland, pulmonary atelectasis, pain in the rectum, chronic catarrh of the sinuses, splanchnoptosis, enlarged spleen in progressive anemia, pain in the spleen, pain in the stomach, prolapsed stomach, sunstroke, incontinence of urine, pain in the uterus and appendages, subinvolution of the uterus and appendages, vasomotor paralysis, vasomotor spasm, congested viscera, whooping cough, ankylosis, adhesions, generalized atonia, indolent liver and gallbladder, and excess fat. The device would not provide an adequate and effective treatment for such conditions.

The devices were misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: No claimant having appeared, the court entered a decree of condemnation against the *Pedasine devices* on April 7, 1953, and a decree of condemnation against the other devices on July 14, 1953. The court ordered that the devices and their labeling be delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

4239. Misbranding of Blake's Mineral Compound. U. S. v. 14 Bags, etc. Motion for summary judgment granted. Decree of condemnation. (F. D. C. No. 33292. Sample Nos. 13531–L, 13532–L.)

LIBEL FILED: June 16, 1952, District of Idaho.

ALLEGED SHIPMENT: On or about October 4 and 11, 1951, and March 3, 1952, the Hy-Life Mineral Co. shipped from Denver, Colo., a number of 105-pound bags of a mineral compound.

PRODUCT: 14 105-pound bags of a mineral compound, 5 cartons of *Blake's Mineral Compound*, and 550 empty cartons in possession of the Globe Seed & Feed Co., Inc., at Twin Falls, Idaho.

RESULTS OF INVESTIGATION: The product contained in the cartons had been repackaged from a portion of a bulk shipment described above. The empty cartons were to be filled with an additional quantity of the product contained from the bulk shipment. All of the cartons had been printed for the consignee in Denver, Colo.

LABEL, IN PART: (Tag) "Hy-Life Mineral Co. Manufacturers of Chemical Products For Livestock Men 2145 Blake Street Denver, Colo."; (bag) "Mineral Compound 105 Lbs. Net."; (carton) "Blake's Mineral Compound * * * Ingredients: (Active) Ammonium Chloride; Potassium Chlorate; Sodium Sulphate; Calcium Carbonate; Tobacco Powder. Red Oxide of Iron is added as a coloring agent * * * Oil of Anise Added * * * Net contents—3½ lbs. Manufactured by Banner Mills Operated by Globe Seed & Feed Co., Inc. Twin Falls, Idaho."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the carton label were false and misleading since the statements represented and suggested that the article was effective in the prevention and treatment of bloat in sheep and cattle, whereas the article was not effective for such purposes: "A chemical preparation which, when mixed with salt as directed, is designed for feeding Sheep and Cattle while pasturing in green Alfalfa, Clover or in

Corn and Wheat fields. * * * 1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * Remove all other salt from your livestock. Place this mixture in troughs conveniently accessible to livestock. Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter."

Further misbranding, Section 502 (a), the name of the article "Blake's Mineral Compound" and the representations on the label that the declared ingredients were active, coupled with the directions for use, namely, "1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * Remove all other salt from your livestock. Place this mixture in troughs conveniently accessible to livestock. Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter. 2. When grain is fed—for example, to dairy cows—mix one 3½ lb. package of Blake's Mineral Compound with only 15 lbs. of finely ground salt. Use this mixture to season the grain. Allow from one to two level tablespoons per head for cattle, or two level teaspoons per head for sheep. In addition to treating the grain ration when one is fed, be certain also to have the mixture described in paragraph one (above) available in troughs," were false and misleading. Such name and representations suggested that the article furnished essential minerals required by sheep and cattle, whereas, ammonium chloride and sodium sulfate, two of the declared active ingredients, are not required by sheep and cattle; and tobacco powder is not a mineral, and, when used as directed, the article furnished inconsequential nutritional amounts of potassium chlorate and calcium carbonate, the two other declared active ingredients.

Further misbranding, Section 502 (a), the statement "Manufactured by Banner Mills Operated by Globe Seed & Feed Co., Inc. Twin Falls, Idaho" appearing on the carton label was false and misleading since the article was not manufactured by Globe Seed & Feed Co., Inc., nor at Twin Falls, Idaho; and Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

The article was misbranded under Section 502 (a) while held for sale after shipment in interstate commerce and under Section 502 (f) (1) when introduced into and while in interstate commerce.

DISPOSITION: The Hy-Life Mineral Co., J. P. Rosenbaum & Co., and Globe Seed & Feed Co., Inc., appeared as joint claimants and filed an answer denying that the product was misbranded. A motion for summary judgment was filed by the Government on November 13, 1952. On March 24, 1953, after considering the briefs and arguments of counsel, the court granted the motion for summary judgement, and on April 7, 1953, handed down the following findings of fact and conclusions of law:

CLARK, *District Judge:* "This cause having come on for hearing on the plaintiff's motion for summary judgment, the Court, after hearing oral argument and considering the pleadings, affidavits, and memoranda submitted by counsel for both parties, hereby makes the following findings of fact and conclusions of law:

FINDINGS OF FACT

"1. The article seized in this action consisted of a number of 105# bags of a mineral compound, the main ingredients of which are ammonium chloride, potassium chlorate, sodium sulfate, calcium carbonate, and tobacco powder.

"2. The seized article was shipped in interstate commerce by the Hy-Life Mineral Company from Denver, Colorado, to Globe Seed & Feed Company, Inc., Twin Falls, Idaho, on or about October 4 and 11, 1951, and March 3, 1952.

"3. When introduced into and while in interstate commerce the labeling of the article consisted of the following written, printed, and graphic matter:

(Tag) Hy-Life Mineral Co. Manufacturers
of Chemical Products For Livestock
Men 2145 Blake Street Denver, Colo.
(Bag) Mineral Compound 105 Lbs. Net

"4. The article was intended for use in the treatment of bloat in sheep and cattle.

"5. When introduced into and while in interstate commerce the labeling of the article did not state that the article was intended to treat 'bloat,' nor did it bear any directions for use in the treatment of that disease.

"6. While held for sale by the Globe Seed & Feed Company, Inc., at Twin Falls, Idaho, after shipment in interstate commerce, the article was accompanied by labeling which read, in part, as follows:

(Carton) Blake's MINERAL COMPOUND
A chemical preparation which, when mixed with salt as directed, is designed for feeding Sheep and Cattle while pasturing in green Alfalfa, Clover or in Corn and Wheat fields.
INGREDIENTS: (Active) Ammonium Chloride; Potassium Chlorate; Sodium Sulphate; Calcium Carbonate; Tobacco Powder.
Red Oxide of Iron is added as a coloring agent * * * Oil of Anise added * * * Net contents—3½ lbs. Manufactured by Banner Mills Operated by Globe Seed & Feed Co., Inc., Twin Falls, Idaho.
1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * REMOVE ALL OTHER SALT FROM YOUR LIVESTOCK. Place this mixture in troughs conveniently accessible to livestock.
Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter.

These statements suggest and imply that the article is effective in the prevention and treatment of bloat in sheep and cattle.

"7. The claimants in this action are the Hy-Life Mineral Company, J. P. Rosenbaum, owner of the Hy-Life Mineral Company, and the Globe Seed & Feed Company, Inc., a corporation.

"8. The Hy-Life Mineral Company and J. P. Rosenbaum, its owner, shipped the seized article in interstate commerce. The Globe Seed & Feed Company, Inc., obtained all right, title, and interest to the article through purchase from the Hy-Life Mineral Company and J. P. Rosenbaum.

"9. In 1945 a seizure action was brought against a quantity of this same article under the name of 'Blake's Stop-Bloat Chemicals' in the United States District Court for the District of Wyoming. It was alleged that the product was misbranded in that it was represented in its labeling as being effective when used as directed in preventing bloat in livestock. These representations were alleged to be false and misleading in that the article would not prevent bloat in livestock. While the claims of preventing bloat were stated in different language in the labeling involved in the 1945 seizure action, the impression made was substantially the same as that conveyed by the labeling involved in the present proceeding, namely, that the article would prevent bloat in livestock. The article involved in the seizure action in the United States District Court for the District of Wyoming consisted essentially of the same ingredients as the article herein seized, although minor quantitative differences exist in the ingredients present. The action of the article when fed to livestock would not be changed by these minor quantitative differences. After trial without a jury, the United States District Court for the District of Wyoming found that the article would not mitigate, treat, cure, or prevent bloat

in livestock and found as a matter of law that the article was misbranded. The Court entered a decree of condemnation and ordered that the seized article be destroyed. This action was No. 2960 Civil, decided March 11, 1946.

"10. The claimant in this proceeding, J. P. Rosenbaum, the owner of the Hy-Life Mineral Company, appeared as claimant and contested the previous action decided in the United States District Court for the District of Wyoming.

"11. Subsequent actions were filed against other shipments of the article involved in this action in 1945 in the United States District Court for the District of Kansas, First Division, Civil Action No. 5366; in 1945 in the United States District Court for the District of Montana, Butte Division; and three other seizure actions in the District of New Mexico in May of 1952, Nos. 2048, 2049, and 2050. All of these actions resulted in default decrees of condemnation.

CONCLUSIONS OF LAW

"On the basis of the foregoing findings of fact, I hereby conclude as a matter of law:

"1. The seized article is a drug within the meaning of 21 U. S. C. 321 (g) (2).

"2. The article of drug was shipped in interstate commerce.

"3. The drug when introduced into and while in interstate commerce was misbranded within the meaning of 21 U. S. C. 352 [502] (f) (1), in that its labeling failed to bear adequate directions for use, since the labeling did not mention the disease condition for which the drug was intended, namely, bloat in sheep and cattle, nor did it bear any directions for use for that disease.

"4. The claimant, the Globe Seed & Feed Company, Inc., is in privity with the claimant, Hy-Life Mineral Company and J. P. Rosenbaum, its owner, having obtained its title to the seized article from the Hy-Life Mineral Company and J. P. Rosenbaum.

"5. The claimants are estopped by the principle of *res judicata* from contesting the issue as to whether the drug is effective in treating or preventing bloat in livestock, this issue having been decided adversely to them in prior litigation.

"6. The drug was misbranded while held for sale after shipment in interstate commerce within the meaning of 21 U. S. C. 352 [502] (a), in that the statements in its labeling which recommended it for the prevention, treatment or cure of bloat in sheep and cattle are false and misleading.

"7. The United States of America, libelant, is entitled to summary judgment as a matter of law since there exists no genuine issue as to any material fact."

In accordance with the above findings of fact and conclusions of law, the court, on April 7, 1953, entered a decree of condemnation and ordered that the product be destroyed.

4240. Misbranding of Dr. David Roberts veterinary drugs. U. S. v. 8 Cartons, etc. (F. D. C. No. 35304. Sample Nos. 20645–L to 20650–L, incl.)

LIBEL FILED: June 16, 1953, District of Minnesota.

ALLEGED SHIPMENT: Between the approximate dates of August 8, 1951, and March 23, 1953, by Dr. David Roberts Veterinary Co., from Waukesha, Wis.

PRODUCT: 8 8-ounce cartons of *Dr. David Roberts Diuretic*, 24 1-pound, 12-ounce cartons of *Dr. David Roberts Special Rx No. 63*, 2 14-pound cartons and 4 cases, each case containing 12 3-pound cartons, of *Dr. David Roberts Herd Iron Tonik for Cows*, 8 3-pound cartons of *Dr. David Roberts Herd Iron Tonik for Sheep*, 2 3-pound cartons and 24 15-ounce cartons of *Dr. David Roberts Worm Seed Rx No. 89*, and 1 12-pound carton of *Dr. David Roberts Poultry Rx No. 62* at Duluth, Minn., together with a number of booklets entitled "The Practical Home Veterinarian," a leaflet entitled "Take Good Care of Your Livestock and Your Livestock Will Take Care of You," and a price list entitled "Full Line of Veterinary Medicines prepared by Dr. David Roberts Veterinary Co.," which accompanied the products.

LABEL, IN PART: (Carton) "Dr. David Roberts Diuretic Active Ingredients: Juniper Berries Anise Licorice Salt Petre Sulphur Inert Ingredients: Rosin Sugar Bicarbonate of Soda Corn Starch 15%," "Dr. David Roberts Special RX No. 63 For Livestock At Breeding Time Ingredients: Nux Vomica (Strychnine 1/12 grs. in each ounce) Carbolic Acid 1.6% Capsicum Demiana Wild Mustard Seed Cantharides Burdock Anise Black Haw Sulphur Corn Starch 24% Locust Beans 32% Feeding Lime," "Dr. David Roberts Herd Iron Tonik For Cows Ingredients: Nux Vomica (strychnine .25 grains in each ounce), Carbolic Acid 1%, Salol, Potassium Iodide, Iron and Copper Sulphate, Colombo Root, Anise, Black Haw, Poke Root, Sulphur, Epsom Salts, Sodium Bicarbonate, Manganese and Cobalt Sulphate. Ingredients: Starch, Phosphorus p. r. Cocoa Shells, Calcium, sugar carbohydrates, Malt products and Yeast vitamins B–G, Vitamin 'D' 2500 U. S. P. Units per ounce," "Dr. David Roberts Herd Iron Tonik For Sheep Active Ingredients: Nux Vomica (strychnine .25 grains in each ounce), Carbolic Acid 1%, Potassium Iodide 1/5%, Iron Sulphate, Copper Sulphate 8/10%, Gentian, Anise, Sulphur, Black Haw, Poke Root, Epsom Salts, Sodium Carbonate, Manganese, Cobalt. Inert Ingredients: Corn Starch, Bone Meal, Salt, Cocoa Shells, Locust Beans, Feeding Lime and Dehydrated Grains, Vitamin 'D' 2500 U. S. P. Units Per Oz.," "Dr. David Roberts Worm Seed Rx No. 89 For Common Worms in Livestock and Poultry Ingredients: Worm Seed (chenopodium) 7%, Quassia, Copper Sulphate 17%, Tobacco Dust (nicotine), Sulphate of Iron, * * * Rosin (comp.), Sulphur, Charcoal, Calcium Carb., Yeast Meal," and "Dr. David Roberts Poultry Rx No. 62 Active Ingredients: Dry Brewers Yeast Carbonate of Iron Capsicum Quassia Copperas Tobacco Mineral Oil Powdered Borax Toasted Bread (ground) Inert Ingredients: Salt Epsom Salts Ground Alfalfa Feeding Lime."

NATURE OF CHARGE: *Dr. David Roberts Diuretic.* Misbranding, Section 502 (a), certain statements in the above-mentioned price list and booklets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for faulty kidney action in all animals, red water in cattle, azoturia or paralysis of the hind parts, and kidney disease in horses. The article was not an adequate and effective treatment for such conditions.

Dr. David Roberts Special Rx No. 63. Misbranding, Section 502 (a), the statements on the carton label and in the above-mentioned price list and booklets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for breeding troubles of cows, mares, and sows, slow breeders or failure to conceive in cows, slow breeding or failure to conceive in mares, and abortion ("Sows Losing Pigs") in sows; that it would stimulate breeding in cows, mares, and sows, and would act as a tonic and a regulator for the genital organs of livestock. The article was not an adequate and effective treatment for such conditions, and it would not fulfill the promises of benefit stated and implied.

Dr. David Roberts Herd Iron Tonik for Cows. Misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned price list, leaflet, and booklets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for cows that were not doing well, overworked cows, eye diseases, fistula, genital organ disorders, superficial itch and skin diseases, such as eczema and mange, lump jaw or actinomycosis, and warts of cattle, calf scours in

nursing calves when administered to the cows, inflammation of the testicles of bulls, and sleeping sickness in horses; that it was an adequate and effective preventive against bloat and ketosis (acetonemia) in cattle; that it would restore cattle to a normal, healthy condition regardless of the condition before using, and keep herds of cattle profitable, healthy, and producing at top quality; and that it would aid digestion, tone up the system, promote vigor, build up the quality of the blood, and restore a normal flow of milk in cows. The article was not an adequate and effective treatment or preventive for such conditions, and it would not fulfill the promises of benefit stated and implied.

Dr. David Roberts Herd Iron Tonik for Sheep. Misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned price list and booklets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for catarrhal fever and colds, indigestion, pregnancy and lambing disease, foot rot, and lung worms in sheep; and that it would restore nervous, rundown, or unthrifty sheep to a normal, healthy condition, and would keep flocks of sheep profitable. The article was not an adequate and effective treatment for such conditions, and it would not fulfill the promises of benefit stated and implied.

Dr. David Roberts Worm Seed Rx No. 89. Misbranding, Section 502 (a), certain statements on the label of the article and in the above-mentioned price list and booklets which represented and suggested that the article was an adequate and effective treatment for removing bots from horses and all species of worms from livestock and poultry were false and misleading since the article was not an adequate and effective treatment for such purposes; the reference on the label to American worm seed (Chenopodium) and tobacco dust (nicotine) was misleading since it represented and suggested that such substances were present in such proportions in the article as to be of therapeutic significance when the article was administered as directed, whereas such was not the case; and the labeling of the article was misleading since it was designated on the label by a name which included the name of one of the ingredients in the article but not all such ingredients even though the names of all such ingredients were stated elsewhere on the label.

Dr. David Roberts Poultry Rx No. 62. Misbranding, Section 502 (a), certain statements in the above-mentioned price list and booklets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for blackhead in turkeys, bowel trouble (coccidiosis), crop bound, diarrhea, gapes, leg weakness, and roup in poultry, and that it would restore poultry to a normal, healthy condition regardless of the condition before using. The article was not an adequate and effective treatment for such conditions, and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: August 26, 1953. Default decree of destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4230) Injunction issued.
[2] (4239) Seizure contested. Contains findings of fact and conclusions of law.

[2] (4239) Seizure contested. Contains findings of fact and conclusions of law.

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4241–4260

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 9, 1954.*

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* For presence of a habit-forming narcotic without warning statement, see Nos. 4248, 4249; omission of, or unsatisfactory, ingredients statements, Nos. 4247–4249, 4252; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4247–4249, 4252; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4247, 4248, 4252.

320999—54

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4241. Misbranding of Amytal Sodium capsules, Seconal Sodium capsules, and sulfadiazine tablets. U. S. v. Parke Drug Co., Samuel M. Larner, and Charles Levine. Pleas of guilty. Fine of $1,000 against company, $350 against Defendant Larner, and $250 against Defendant Levine. Each defendant also placed on probation for 1 year. (F. D. C. No. 34354. Sample Nos. 37336–L, 37702–L, 37706–L, 37708–L, 37891–L, 37895–L, 37900–L.)

INFORMATION FILED: April 6, 1953, District of New Jersey, against the Parke Drug Co., a corporation, Asbury Park, N. J., Samuel M. Larner and Charles Levine, pharmacists for the corporation.

NATURE OF CHARGE: On or about May 6, 13, 20, 27, and 28, 1952, while a number of *Amytal Sodium capsules*, *Seconal Sodium capsules*, and *sulfadiazine tablets* were being held for sale at the Parke Drug Co., after shipment in interstate commerce, various quantities of the drugs were dispensed upon requests for refills of prescriptions for such drugs, without obtaining authorization by the prescriber. The corporation was charged with causing the acts of dispensing involved in each of the 7 counts of the information, Defendant Larner was joined as a defendant in 3 counts, and Defendant Levine was joined as a defendant in the other 4 counts of the information. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: November 16, 1953. Pleas of guilty having been entered by the defendants, the court fined the corporation $1,000, Defendant Larner $350, and Defendant Levine $250. The court also placed each defendant on probation for 1 year.

4242. Misbranding of Dexedrine Sulfate tablets and Seconal Sodium capsules. U. S. v. Alex H. Altshuler (Seldale Drug). Plea of guilty. Defendant fined $500 and placed on probation for 3 years. (F. D. C. No. 34361. Sample Nos. 48281–L, 48282–L, 48284–L.)

INFORMATION FILED: April 21, 1953, District of Minnesota, against Alex H. Altshuler, trading as the Seldale Drug, St. Paul, Minn.

NATURE OF CHARGE: On or about April 29 and May 9, 1952, while a number of *Dexedrine Sulfate tablets* and *Seconal Sodium capsules* were being held for sale at the Seldale Drug, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be dispensed upon requests for refills of written prescriptions for such drugs, without obtaining authorization by the prescriber. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: December 28, 1953. The defendant having entered a plea of guilty, the court fined him $500 and placed him on probation for 3 years.

4243. Misbranding of pentobarbital sodium capsules and secobarbital sodium capsules. U. S. v. Samuel S. Steinberg. Plea of guilty. Sentence of 3 months in jail. (F. D. C. No. 35115. Sample Nos. 3029–L, 72239–L.)

INDICTMENT RETURNED: April 20, 1953, District of Columbia, against Samuel S. Steinberg.

NATURE OF CHARGE: On or about December 23, 1952, and April 18, 1953, the defendant dispensed a number of *pentobarbital sodium capsules* and *secobarbital sodium capsules* without prescriptions therefor from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: December 18, 1953. The defendant having entered a plea of guilty, the court sentenced him to serve 6 months in jail.

On February 14, 1954, upon motion of the defendant, an order was entered reducing the sentence to 3 months in jail.

4244. Misbranding of pentobarbital sodium capsules and paraldehyde. U. S. v. Samuel L. Cohen (Bunker Hill Drug). Plea of not guilty. Verdict of guilty. Fine of $1,000 and sentence of 6 months in jail. Jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 34308. Sample Nos. 6587–L to 6589–L, incl., 44571–L.)

INFORMATION FILED: February 24, 1953, District of Massachusetts, against Samuel L. Cohen, trading as Bunker Hill Drug, Charlestown, Mass.

NATURE OF CHARGE: On or about July 2, 7, and 9, 1952, while a number of *pentobarbital sodium capsules* and a quantity of *paraldehyde* were being held for sale at Bunker Hill Drug, after shipment in interstate commerce, the defendant caused various amounts of the *pentobarbital sodium capsules* and a quantity of *paraldehyde* to be dispensed without prescriptions from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: The defendant having entered a plea of not guilty, the case came on for trial before the court and jury on December 3, 1953. The trial was concluded on the same day, with the return of a verdict of guilty by the jury and the imposition of a fine of $1,000 and a sentence of 6 months in jail against the defendant. The jail sentence was suspended, and the defendant was placed on probation for 2 years.

4245. Misbranding of apiol and ergotin compound capsules and sulfadiazine tablets. U. S. v. Isadore Shapiro (Ted Shapiro's Drugs). Plea of nolo contendere. Fine of $250 on count 1. Imposition of sentence suspended on remaining 4 counts of information and defendant placed on probation for 3 years. (F. D. C. No. 34831. Sample Nos. 25784–L, 41531–L, 41746–L to 41748–L, incl.)

INFORMATION FILED: May 6, 1953, District of New Jersey, against Isadore Shapiro, trading as Ted Shapiro's Drugs, Camden, N. J.

NATURE OF CHARGE: On or about July 14, September 30, and October 2 and 4, 1952, while a number of *apiol and ergotin compound capsules* and *sulfadiazine tablets* were being held for sale at Ted Shapiro's Drugs, after shipment in

interstate commerce, the defendant caused various quantities of the drugs to be dispensed without prescriptions from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: November 20, 1953. The defendant having entered a plea of nolo contendere, the court fined him $250 on count 1, suspended the imposition of sentence on the remaining 4 counts of the information, and placed him on probation for 3 years.

4246. Misbranding of sulfathiazole tablets. U. S. v. Meyer Goldberg. Plea of guilty. Fine, $600. (F. D. C. No. 35116. Sample Nos. 41532–L, 41542–L, 66951–L.

INFORMATION FILED: July 21, 1953, Eastern District of Pennsylvania, against Meyer Goldberg, Philadelphia, Pa.

NATURE OF CHARGE: On or about January 22, 26, and 29, 1953, while a number of *sulfathiazole tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drug. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed tablets being misbranded while held for sale.

DISPOSITION: December 10, 1953. The defendant having entered a plea of guilty, the court fined him $600.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4247. Misbranding of methamphetamine hydrochloride tablets and dextro-amphetamine sulfate tablets. U. S. v. Fred Meyer, Inc. Plea of nolo contendere. Fine, $500. (F. D. C. No. 33753. Sample Nos. 28973–L, 29179–L to 29186–L, incl., 29188–L, 29189–L, 29892–L, 30435–L.)

INFORMATION FILED: September 14, 1953, District of Oregon, against Fred Meyer, Inc., Portland, Oreg.

ALLEGED VIOLATION: On or about October 17, 18, 19, and 30, and November 7, 1951, while a number of *methamphetamine hydrochloride tablets* and *dextro-amphetamine sulfate tablets* were being held for sale at Fred Meyer, Inc., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), portions of the repackaged *methamphetamine hydrochloride tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), portions of the repackaged *methamphetamine hydrochloride tablets* and all of the repackaged *dextro-amphetamine sulfate tablets* failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), the labels of the repackaged *dextro-amphetamine sulfate tablets* and of portions of the repackaged *methamphetamine hydrochloride tablets* failed to bear the common or usual name of each active ingredient of such drugs; and, Section 502 (f) (2), the labeling of the re-

packaged *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: November 10, 1953. The defendant having entered a plea of nolo contendere, the court fined it $500.

4248. Misbranding of dextro-amphetamine sulfate tablets, methyltestosterone tablets, tablets containing a mixture of pentobarbital and aspirin, and liquid mixture containing, among other things, phenobarbital. U. S. v. Robert T. Royce (Royce Drug Store), and Aubrey E. Simmons. Plea of nolo contendere by Defendant Royce and plea of guilty by Defendant Simmons. Fine of $120 against Defendant Royce and $105 against Defendant Simmons. (F. D. C. No. 32734. Sample Nos. 15446–L to 15448–L, incl., 15450–L, 16451–L, 16453–L, 16456–L, 16458–L.)

INFORMATION FILED: September 18, 1952, Western District of Oklahoma, against Robert T. Royce, trading as the Royce Drug Store, Lawton, Okla., and Aubrey E. Simmons, a pharmacist in the store.

ALLEGED VIOLATION: On or about October 11, 13, 15, and 22, 1951, while a number of *dextro-amphetamine sulfate tablets*, *methyltestosterone tablets*, *tablets containing a mixture of pentobarbital and aspirin*, and *liquid mixture containing, among other things, phenobarbital* were being held for sale at the Royce Drug Store, after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the dispensed drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged drugs, with the exception of the *tablets containing a mixture of pentobarbital and aspirin* and a portion of the *liquid mixture containing, among other things, phenobarbital*, failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *tablets containing a mixture of pentobarbital and aspirin* and the repackaged *liquid mixture containing, among other things, phenobarbital* were drugs for use by man and contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of such drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith a statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), a portion of the repackaged *dextro-amphetamine sulfate tablets* and all of the *methyltestosterone tablets* failed to bear a label containing the common or usual name of each active ingredient of the drugs.

DISPOSITION: On November 21, 1952, upon a plea of nolo contendere by Defendant Royce, the court fined him $120. On April 2, 1954, upon a plea of guilty by Defendant Simmons, the court fined him $105.

4249. Misbranding of Dexedrine Sulfate tablets and Seconal Sodium capsules. U. S. v. Keller Drug Co. Plea of guilty. Fine of $800 and probation for 2 years. (F. D. C. No. 34817. Sample Nos. 35069–L, 35532–L, 48393–L, 48395–L.)

INFORMATION FILED: April 21, 1953, District of Minnesota, against the Keller Drug Co., a corporation, Minneapolis, Minn.

ALLEGED VIOLATION: On or about February 6, 12, 27, and 28, 1952, while a number of *Dexedrine Sulfate tablets* and *Seconal Sodium capsules* were being held for sale at the Keller Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the label of the repackaged *Dexedrine Sulfate tablets* failed to bear the common or usual name of each active ingredient of the tablets.

DISPOSITION: December 14, 1953. The defendant having entered a plea of guilty, the court fined it $800 and placed it on probation for 2 years.

4250. Misbranding of Green Kaps. U. S. v. Lawrence F. Rathbun (Asthmacine Distributing Co.). Plea of guilty. Fine of $350, plus costs. (F. D. C. No. 33793. Sample No. 54728–L.)

INFORMATION FILED: August 13, 1953, Northern District of Illinois, against Lawrence F. Rathbun, trading as the Asthmacine Distributing Co., Chicago, Ill.

ALLEGED SHIPMENT: On or about August 21, 1952, from the State of Illinois into the State of Michigan.

LABEL, IN PART: "Green-Kaps A Dietary Supplement."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the condition for which it was intended, namely, delayed menstruation.

DISPOSITION: November 23, 1953. The defendant having entered a plea of guilty, the court fined him $350, plus costs.

4251. Misbranding of El Rancho Adolphus products. U. S. v. 3 Cans, etc. (F. D. C. No. 35350. Sample Nos. 45551–L to 45554–L, incl., 45556–L.)

LIBEL FILED: July 8, 1953, District of Massachusetts.

ALLEGED SHIPMENT: A quantity of *papaya sirup* was shipped by the Lakewood Foods Co., from Miami, Fla., on or about May 26, 1953, and the other products were shipped by El Rancho Adolphus Products, Inc., from Scranton, Pa., and from Hohensee Park, Jermyn, Pa., on or about June 8, 15, and 16, 1953.

PRODUCT: 3 cans each containing 30 packages, of *peppermint tea leaves*, 8 cases, each containing 12 bottles, of *apple juice concentrate*, 9 cases, each containing 4 bottles, of *papaya sirup*, 1 case, containing 58 packages, of *herb laxative*, and 2 cases, each containing 24 packages, of *broth concentrate* at Brookline, Mass.

RESULTS OF INVESTIGATION: At a lecture delivered in Boston, Mass., on June 16, 1953, Adolphus Hohensee had available for sale to his audience a booklet entitled "Lecture Series on Health and Progress—Fasting * * * By Adolphus Hohensee * * * Published at El Rancho Adolphus Home Of Scientific Living, Inc. Post Office Box 910 Scranton, Pa.," which contained statements relating to the conditions and purposes for which the products were intended. During the course of the lecture, Mr. Hohensee informed his audience that the products were available at a store in Brookline, Mass.

LABEL, IN PART: (Packages) "El Rancho Adolphus Brand Genuine-Select Imported Peppermint Tea Leaves * * * Net Weight 3 Ozs. [or "Herb Laxative (Minted) * * * Net Weight 3 Ozs."] Distributed by El Rancho Adolphus Products, Inc. Scranton, Pa."; (bottles) "El Rancho Adolphus Brand Pure Apple Juice Concentrate * * * One Quart [or "Papaya Syrup One Gallon Net"] Distributed by El Rancho Adolphus Products, Inc. Hohensee Park, Jermyn, Pa. [or "Scranton, Pa."]"; and (packages) "El Rancho Adolphus Broth Concentrate * * * Instant Vegetable Puree * * * Net weight 8 Ozs. El Rancho Adolphus Products, Inc. * * * Scranton, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the conditions and for the purposes for which they were intended, namely, (all articles) for rejuvenating the body by allowing the blood to flow freely and the renewal processes to exceed those of disintegration; for normalizing the body's chemistry, thereby permitting the body to regain its equilibrium; for improving the senses of sight, smell, hearing, and touch; for causing wrinkles, pimples, and blotches to disappear and the skin to regain its youthful appearance; for regenerating most of the organs and glands; for causing growths, deposits, effusions, dropsicals (sic), swellings, and infiltrations to be absorbed and used to support the vital organs; for strengthening weak hearts and conserving nerve energy, thereby enabling the vital organs to improve in force and function; for purging the blood of poisons and clogging waste and decaying diseased cells; for enabling the body to concentrate on building healthy or better material to replace that which is cast out, thus effecting regeneration and keeping the body active and vigorous; (*apple juice concentrate*) for cleansing the body; (*peppermint tea leaves*) for acting as an alkalizer and body cleanser and treating colic, headache, and rheumatism; (*broth concentrate*) for cleansing and rebuilding the body and loosening deadly toxins from people who are highly toxic; and (*apple juice concentrate* used with olive oil) for treating gallstones and kidney stones. The articles were misbranded in the above respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: August 25, 1953. Default decree of condemnation and destruction.

4252. Misbranding of soya lecithin. U. S. v. 2 Cases * * *. (F. D. C. No. 35409. Sample No. 82093–L.)

LIBEL FILED: On or about September 3, 1953, Western District of Missouri.

ALLEGED SHIPMENT: On or about June 11, 1953, by Wolf Foods, Inc., from Ellinwood, Kans.

PRODUCT: 2 cases, each containing 12 unlabeled, 8-ounce bottles, of *soya lecithin* at Kansas City, Mo.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the label failed to bear the common or usual name of the article, namely, soya lecithin; and, Section 502 (f) (1), the label of the article failed to bear adequate directions for use in the treatment of arthritis, rheumatism, skin conditions, and circulatory disorders, which were the conditions for which the article was intended.

DISPOSITION: October 28, 1953. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4253. Adulteration of pink tablets. U. S. v. 1,600 Tablets * * *. (F. D. C. No. 35656. Sample No. 61732–L.)

LIBEL FILED: September 30, 1953, District of Nebraska.

ALLEGED SHIPMENT: On or about November 28, 1952, from St. Louis, Mo.

PRODUCT: 1,600 *pink tablets* at Kearney, Nebr. Examination showed that the product contained not more than 20 percent of the declared amount of nitroglycerin.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 1/100 grain of nitroglycerin per tablet. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: November 4, 1953. The owner of the product having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

4254. Adulteration and misbranding of vitamin capsules. U. S. v. 39 Cartons * * *. (F. D. C. No. 34913. Sample No. 17244–L.)

LIBEL FILED: March 30, 1953, Southern District of California.

ALLEGED SHIPMENT: On or about November 9 and December 16 and 23, 1952, by the American Pharmaceutical Co., from New York, N. Y.

PRODUCT: 39 cartons, each containing 12 100-capsule bottles, of *vitamin capsules* at Los Angeles, Calif.

LABEL, IN PART: (Bottle) "100 APC Capsules Belexon Fortified Vitamin B-Complex with Liver, Folic Acid and Vitamin B_{12} * * * A rich source of all B-complex Vitamins and a stimulant of the hematopoietic system in nutri-

tional, secondary and macrocytic anemias * * * Each Capsule Contains: * * * Thiamine Hydrochloride (B_1) 5 mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 5 milligrams of vitamin B_1 per capsule.

Misbranding, Section 502 (a), the label statement "Each Capsule Contains: * * * Thiamine Hydrochloride (B_1) 5 mg." was false and misleading as applied to the article, which contained less than the declared amount of thiamine hydrochloride (B_1).

The article was adulterated and misbranded in the above respects when introduced into and while in interstate commerce.

The libel alleged also that another lot of vitamin capsules was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: July 23, 1953. The American Pharmaceutical Co., New York, N. Y., claimant, having consented to the entry of a decree, the court ordered that a portion of the vitamin capsules having the status of drugs be released to the claimant and that the remainder of the vitamin capsules having the status of drugs and all of the vitamin capsules having the status of foods be condemned and destroyed.

4255. Adulteration and misbranding of vitamin tablets. U. S. v. 201 Bottles, etc. (F. D. C. No. 35312. Sample No. 38087-L.)

LIBEL FILED: July 10, 1953, Southern District of New York.

ALLEGED SHIPMENT: On or about April 24, May 20, 21, and 26, and December 2, 1952, and January 29, 1953, from Cleveland, Ohio.

PRODUCT: 201 120-tablet bottles, 1,320 60-tablet bottles, 2,448 6-tablet bottles, and 2 drums containing 2,500 tablets and 30,000 tablets, respectively, of *vitamin tablets* at New York, N. Y.

Analyses showed that the tablets contained 43 percent of the declared amount of vitamin B_1 (thiamine hydrochloride).

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the tablets differed from that which they purported and were represented to possess, namely, 2.0 milligrams of thiamine hydrochloride per tablet.

Misbranding, Section 502 (a), the label statement "Each Tablet Contains: Thiamine Hydrochloride . . . . 2.0 mg." was false and misleading as applied to the article, which contained less than 2.0 milligrams of thiamine hydrochloride per tablet.

The article was alleged to be adulterated and misbranded while held for sale after shipment in interstate commerce.

The libel alleged also that another article, vitamin and mineral tablets, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 20794.

DISPOSITION: December 15, 1953. Default decree of condemnation and destruction.

4256. Adulteration and misbranding of vitamin tablets. U. S. v. 172 Bottles, etc. (F. D. C. No. 35356. Sample Nos. 18637-L, 39987-L.)

LIBEL FILED: July 29, 1953, District of Arizona.

ALLEGED SHIPMENT: On or about February 2 and 16 and March 10, 12, and 18, 1953, by Associated Labs., Inc., from New York, N. Y.

PRODUCT: 172 120-tablet bottles and 324 30-tablet bottles of *vitamin tablets* at Phoenix, Ariz. Examination showed that the tablets had deficiencies in vitamin B_1 ranging from 15 percent to 39 percent and in vitamin C ranging from 43 percent to 86 percent.

LABEL, IN PART: (Bottle) "The Hemate Formula Three tablets (Daily Dose) contain: Vitamin B_1 (Thiamine Hydrochloride) . . . . 15 Mg. * * * Vitamin C (Ascorbic Acid) . . . . 150 Mg. * * * Three Hemate Formula Tablets provide 15 times the minimum adult daily requirement (MADR) of Vitamin B_1; 5 times the MADR of Vitamin C."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 15 milligrams of vitamin B_1 and less than 150 milligrams of Vitamin C per 3 tablets.

Misbranding, Section 502 (a), the label statement "Three tablets * * * contain: Vitamin B_1 * * * 15 Mg. * * * Vitamin C * * * 150 Mg." was false and misleading as applied to the article, which contained less than 15 milligrams of vitamin B_1 and less than 150 milligrams of vitamin C per 3 tablets.

DISPOSITION: December 10, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE *

4257. Action to enjoin and restrain violations of Sections 301 (a) and 301 (k) with respect to Testone wheat germ oil capsules. U. S. v. Morris Silfan and Harry Rick (Canal Medical Products), Seward Laboratories, Inc., and Leo Savitch. Consent decree granting injunction. (Inj. No. 263.)

COMPLAINT FILED: March 13, 1953, Southern District of New York, against Morris Silfan and Harry Rick, trading as Canal Medical Products, New York, N. Y., and against Seward Laboratories, Inc., New York, N. Y., and Leo Savitch, president of the corporation.

NATURE OF CHARGE: The complaint alleged that the defendants were engaged in the business of packaging and relabeling capsules of wheat germ oil and distributing and selling them as *Testone wheat germ oil capsules* and that, in the conduct of such business, the defendants employed the following method of operation:

(a) Quantities of wheat germ oil capsules were purchased in bulk from an Illinois firm and, upon their receipt at New York, N. Y., and while held for sale on the premises of Seward Laboratories, Inc., they were repacked into bottles and relabeled;

(b) The defendants solicited orders by mail for the capsules and, following the receipt of such orders, introduced the capsules into interstate commerce;

(c) To explain the uses of the capsules and to permit their distribution, the defendants caused the capsules to be accompanied by labeling consisting of leaflets entitled "Men Past 40 if You have any of These Symptoms" and

* See also Nos. 4254–4256.

"Want proof of Testone's Effectiveness?" and an order blank headed "Don't Delay! * * * Rush Your Testone Order Today."

The complaint alleged further that the defendants, in employing the above method of operation for their business, were violating Section 301 (k) by causing the capsules of wheat germ oil to be relabeled while held for sale after shipment in interstate commerce, which act resulted in the capsules being misbranded under Section 502 (a), in that the label on the bottles containing the capsules and the labeling accompanying the capsules contained statements which represented and suggested that the capsules contained hormonal activity equivalent to therapeutically significant amounts of testosterone and estrone; that the capsules were an adequate and effective treatment for male hormone deficiency, loss of sex urge, sleeplessness, irritability, lack of vigor, nervousness, loss of muscle power, loss of pep, tiredness, and premature old age; and that the capsules were effective to restore men to a life of vigor, vitality and sex enjoyment. These statements were false and misleading in that the capsules did not contain hormonal activity equivalent to therapeutically significant amounts of testosterone and estrone; the capsules were not an adequate and effective treatment for the conditions stated; and they were not effective to restore men to a life of vigor, vitality, and sex enjoyment.

The complaint alleged further that the defendants were violating Section 301 (a) by causing the introduction and the delivery for introduction, into interstate commerce, of the capsules, which were misbranded as described above.

DISPOSITION: On May 13, 1953, the court entered a temporary restraining order enjoining the defendants from the acts complained of. On June 18, 1953, the defendants having consented to the entry of a decree, the court entered a decree permanently enjoining the defendants (1) from shipping in interstate commerce *Testone wheat germ oil capsules* or any similar drug bearing a label or accompanied by labeling containing false and misleading statements of the nature described in the complaint, and (2) from causing any act to be done with respect to any such drug while held for sale after shipment in interstate commerce, which would result in such drug bearing a label or accompanied by labeling containing statements of the nature described in the complaint.

4258. Misbranding of vitamin B_1 tablets. U. S. v. 275 Cards * * *. (F. D. C. No. 35638. Sample No. 47534-L.)

LIBEL FILED: September 17, 1953,, Southern District of Texas.

ALLEGED SHIPMENT: On or about May 20, 1953, from Newark, N. J.

PRODUCT: *Vitamin B_1 tablets.* 275 cards, to each of which was attached a cellophane envelope containing 4 tablets at Houston, Tex., in possession of the consignee, the McDonald Prescription Laboratories, Inc.

RESULTS OF INVESTIGATION: The tablets were shipped in interstate commerce unlabeled and, upon their receipt by the consignee, were repackaged by attaching a printed card to each four tablets in a cellophane envelope.

LABEL, IN PART: (Card) "Four Tablets Orange Vitamin B-1 100 mg. * * * for Adults Only * * * McDonald Laboratories, Inc., Houston, Texas."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labeling of the article, namely, the card attached to the envelope of tablets, were false and misleading. The statements represented that the article was

an effective treatment for physical strain, overwork, mental fatigue, nervous tension, excessive alcoholism, loss of sleep, lack of energy and pep, laziness, hangovers, and mental strain, and that the article would cause one to feel good again and look better and nicer. The article was not an adequate and effective treatment for such conditions, and it would not effect such purposes. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 27, 1953. McDonald Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

4259. Misbranding of Ko-rekT dental device. U. S. v. Demetrie C. Siampaus (Siampaus Mfg. Co.). Plea of not guilty. Tried to the jury. Verdict of not guilty on count 1 and verdict of guilty on count 2. Sentence of 90 days in jail suspended. Costs assessed and defendant placed on probation for 1 year. (F. D. C. No. 33788. Sample Nos. 33667–L, 46538–L.)

INFORMATION FILED: August 11, 1953, District of Nebraska, against Demetrie C. Siampaus, trading as the Siampaus Mfg. Co., Omaha, Nebr.

ALLEGED SHIPMENT: On or about January 1 and March 13, 1952, from the State of Nebraska into the States of Illinois and Louisiana.

PRODUCT: Examination showed that the *Ko-rekT dental device* consisted essentially of 2 counter-rotating rubber discs mounted on metal shafts turned by a handcrank for the purpose of cleaning the teeth and massaging the gums.

NATURE OF CHARGE: Count 1. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device, consisting of a cardboard carton insert headed "Throw Away Your Tooth Brush," were false and misleading. The statements represented and suggested that the device was adequate and effective for the prevention and treatment of bad breath, tartar formation, infected gums and their complications, tooth decay, and pyorrhea, and that the use of the device would assure a healthy mouth. The device was not adequate and effective for the prevention and treatment of the conditions mentioned, and the use of the device would not assure a healthy mouth.

Count 2. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device, consisting of a cardboard carton insert headed "Throw Away Your Tooth Brush," circulars headed "Turn On That Smile with Ko-rekT," and "The Dialogue Below Reveals the Weakest and Therefore the Most Dangerous Part of Our Body," and a leaflet headed "Throw Away Your Tooth Brush," were false and misleading. The statements represented and suggested that the device was adequate and effective for the prevention and treatment of bad breath, tartar formation, infected gums and their complications, tooth and gum trouble, tooth decay, toothache, pyorrhea, infected teeth, loss of teeth, loose teeth, and recession of the gums; that use of the device would assure healthy gums, healthy mouth, good health, and increased longevity; and that the device would rebuild the teeth and jaw bone and preserve youthful appearance. The device was not adequate and effective for the prevention and treatment of the conditions mentioned, and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: December 12, 1953. The defendant having entered a plea of not guilty, the case came on for trial before the court and jury. At the conclusion of the trial, the jury returned a verdict of not guilty on count 1 and a verdict of guilty on count 2. The court sentenced the defendant on count 2 of the information to 90 days in jail, but suspended this sentence and placed the defendant on probation for 1 year. As a special condition of the probation, the defendant was ordered to pay the costs of the prosecution.

DRUG FOR VETERINARY USE

4260. Misbranding of Giatol. U. S. v. 14 Jugs * * *. (F. D. C. No. 35628. Sample No. 61563–L.)

LIBEL FILED: September 16, 1953, District of Kansas.

ALLEGED SHIPMENT: On or about November 20, 1952, by the Peerless Serum Co., from Kansas City, Mo.

PRODUCT: 14 jugs of *Giatol* at Kansas City, Kans.

LABEL, IN PART: (Jug) "MVSC 1 Gallon Giatol (Tasteless) Each Ounce Contains Active Ingredients: Potassium Guaiacolsulfonate 10%, Sodium Sulphocarbolate, Ammonium Chloride 15% Inert Ingredients: Oil Anise, Caramel, Glycerinated Base."

NATURE OF CHARGE: Misbranding Section 502 (a), certain statements on the label of the article, which represented and suggested that the article was an adequate and effective treatment for common inflammatory respiratory disorders of large animals, swine, and fowls, were false and misleading since the article was not an adequate and effective treatment for such conditions.

DISPOSITION: November 19, 1953. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4241 TO 4260

PRODUCTS

[1] (4244, 4259) Prosecution contested.

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4244, 4259) Prosecution contested.
[2] (4257) Injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4244, 4259) Prosecution contested.
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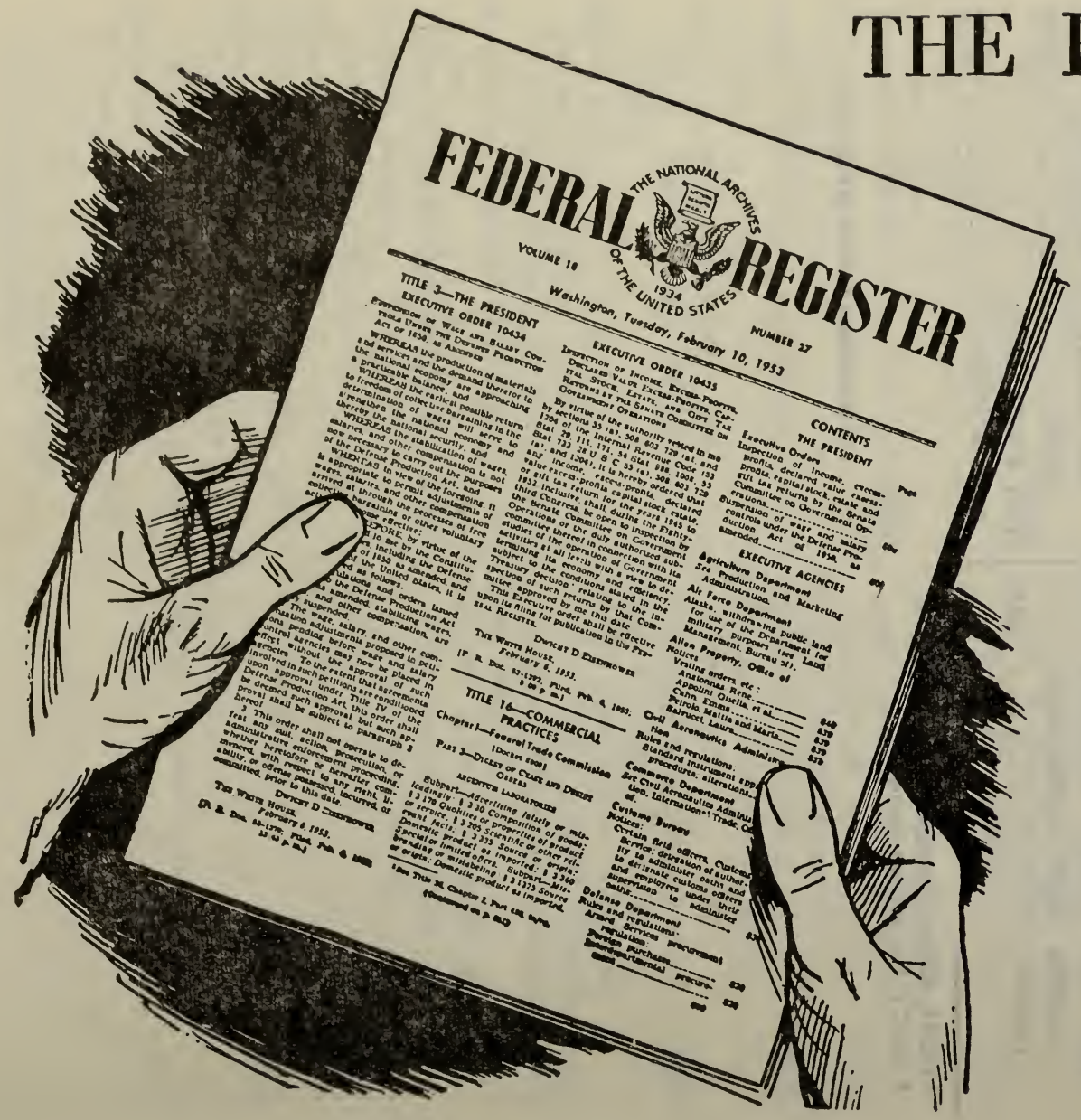

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